EXHIBIT B28

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF NEW JERSEY

- - -

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	:	NO. 16-2738 (FLW) (LHG)
THIS DOCUMENT RELATES TO ALL CASES	:	

- - -

March 26, 2019

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Videotaped deposition of IE-MING SHIH, M.D., Ph.D., taken pursuant to notice, was held at Venable, LLP, 750 East Pratt Street, Baltimore, Maryland, beginning at 9:06 a.m., on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

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I N D E X

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Testimony of:

IE-MING SHIH, M.D., Ph.D.

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E X H I B I T S

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NO.	DESCRIPTION	PAGE
Shih-1	Notice of Deposition	13
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Shih-3	Curriculum Vitae Ie-Ming Shih, M.D., Ph.D.	17
Shih-4	Study Report to Determine Whether Chronic Inflammation Causes Ovarian Cancer (Shih)	18
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Direction to Witness Not to Answer
PAGE LINE
None.

Request for Production of Documents
PAGE LINE
None.

Stipulations
PAGE LINE
None.

Questions Marked
PAGE LINE
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THE VIDEOGRAPHER: We are now on the record.

My name is Daniel Holmstock. I'm the videographer for Golkow Litigation Services.

Today's date is March 26, 2019.

The time on the video screen is 9:06 a.m.

This video deposition is being held at the Law Offices of Venable LLP, at 750 East Pratt Street, Suite 900 in Baltimore, Maryland, In Re Johnson & Johnson Talcum Powder Products Marketing, Sales Practices, and Products Liability Litigation, MDL number 2738, pending before the United States District Court for the Eastern District of New Jersey.

Our deponent today is Dr. Ie-Ming Shih.

Counsel for appearances will be noted on the stenographic

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record.
Our court reporter is Michelle Gray, who will now administer the oath.
- - -
... IE-MING SHIH, M.D., Ph.D., having been first duly sworn, was examined and testified as follows:
- - -
EXAMINATION
- - -
BY DR. RESTAINO:
Q. Good morning, Dr. Shih.
A. Good morning.
Q. My name is John Restaino, and I will be the attorney asking you some questions today. I note from the materials we have received that you have been deposed before, correct?
A. Correct.
Q. But I still -- there's still a few things that I want to go over because I heard you talk about water before the deposition started. We will

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be taking a break about every hour or so; however, in between that period of time, if you need to take a break for whatever reason, you just let us know. Do you understand?
A. Yes.
Q. Today is not going to be a memory test for you. So if you need to review documents, it's open book.
And if you -- and it's not a physical test. So once again, feel free to call for a break whenever you need to if we don't. Do you understand that?
A. Okay.
Q. Now, it's important that you let me know if you don't understand my question. If I become tongue-tied or I use different terminology that you're not used to, let me know and I'll repeat the question. But if you answer a question, the presumption will be that you understood the question. Agreed?
A. I will try my best to answer your question.

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Q. And I will too. And so far we've been doing fine. But there's the court reporter to your right and my left, and she's going to try to take down everything we say. And if we -- all of us were having a normal conversation on a Friday evening somewhere, it's not uncommon to step on each others' sentences without being rude.
But today, if we do that, then in essence we are being rude to the court reporter. So I will do my best to listen for that final period in your answer, if you will do your best to listen for the question mark on mine. Agreed?
A. Okay.
Q. Now, I'm going to hand you what was previously marked this morning as Plaintiffs' Exhibit Number 1, which is the notice of the deposition.
MR. ROTMAN: I handed you one earlier, right?
DR. RESTAINO: Yes, I gave

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it back to Michelle.
MR. ROTMAN: These are the other copies.
(Document marked for identification as Exhibit Shih-1.)
BY DR. RESTAINO:
Q. Doctor, have you seen that before?
A. I remember I saw it --
Q. Okay.
A. -- recently.
Q. If you would turn to Page 4, it becomes the language that's most germane to this morning. You see Number 1, we're requesting your most current curriculum vitae.
Have you provided that to us?
A. I believe so.
Q. Thank you.
Number 2 is copies of any materials that pertain to your retention or payment for services as an expert.

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And have you provided, for example, any retainer agreement that you may have?
A. I don't remember I have a retention agreement.
Q. Okay. Have you provided any documents, invoices, for the time that you have incurred so far in the litigation since you've been retained as an expert?
A. I sent J&J attorney my invoice.
Q. This morning I was provided with an invoice for the draft of expert opinion report dated January 19, 2019. And it states from December 12th to Jan -- of 2018 to January 19th of 2019.
And this invoice is for a total of 18 hours at $800 an hour and $14,400. Does that sound familiar --
MS. MILLER: Can we have a copy of that?
THE WITNESS: Can I see it? Can I see the document?
BY DR. RESTAINO:

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Q. Yes.
A. And can I review it?
MS. MILLER: Dr. Shih, it's redacted because the work you did is confidential, so we blacked this out.
THE WITNESS: Okay. Understand.
MS. MILLER: This is not the way it looked when you sent it to us.
BY DR. RESTAINO:
Q. Does that look familiar, sir?
A. Yes.
Q. Does that look accurate?
A. Correct.
Q. And may I assume that you have put in more hours since January 19th of 2019?
A. I spent additional times on this matter.
Q. Okay. Can you estimate for us how much more time you have spent

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since January 19, 2019, on this matter?
A. I do not have an exact number, because this is still ongoing, and I'm very busy. But I would give you my estimation. About 90 hours, plus/minus 15 hours.
Q. Okay. Have you provided to counsel and through counsel to us any records that you may have in the sense of notes, draft materials, anything that comprise your folder, for example, on the study you have conducted?
MS. MILLER: Wait. Objection. If you're talking about draft materials related to his report, that would be privileged, as you know. Are you asking for draft materials related to his report, or are you only asking about his -- what you're calling his study?
DR. RESTAINO: His study.
MS. MILLER: Okay. Can you explain what you mean by his

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study.
BY DR. RESTAINO:
Q. You have attached to your expert report in the back a document that is a study of analysis that you've conducted of histopathology slides, correct?
A. Could you show me where you are talking about?
Q. Sure. Why don't we go ahead, and I'm going to hand you what we have marked as Exhibit Number 2.
(Document marked for identification as Exhibit Shih-2.)
BY DR. RESTAINO:
Q. And this is your expert report. This obviously, you're going to want to keep open and next to you.
MR. ROTMAN: John, give me one, please.
(Document marked for identification as Exhibit Shih-3.)

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BY DR. RESTAINO:
Q. I'm going to hand you what we have marked as Exhibit Number 3. This is titled "Curriculum Vitae Version February 8, 2019."
(Document marked for identification as Exhibit Shih-4.)
BY DR. RESTAINO:
Q. Exhibit 4 is a document titled "Study Report to Determine Whether Chronic Inflammation Causes Ovarian Cancer."
MS. MILLER: This isn't numbered. Do you have one with a sticker?
DR. RESTAINO: Sorry. That one was for you.
THE WITNESS: I would like to make sure these are my copies.
BY DR. RESTAINO:
Q. Okay. What do you mean by making sure that it's your copy?
A. There is no missing pages

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and additional material.
Q. You are now looking at your -- the exhibit that's your study report, sir?
A. I want to make sure there's no missing pages or additional material inserted.
Q. Sir, are you finished?
A. I guess so.
Q. Okay. Sir, do you have your curriculum vitae which we've marked as Exhibit 3 and you have gone through, do you have that document memorized?
A. Could you repeat your question one more time?
Q. Your -- your CV that you just went through, do you have that document memorized in your mind?
MS. MILLER: Objection.
THE WITNESS: What do you mean memorize?
BY DR. RESTAINO:
Q. Do you know it by heart? If I was to ask you to write down what

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publication Number 123 is, could you tell me without looking?
MS. MILLER: Objection.
THE WITNESS: I know my right quote, but I cannot remember every word and sequence, if you want to test my memory.
BY DR. RESTAINO:
Q. No, sir. I don't want to test your memory, but you just spent a lot of time going through your CV -- CV to see if anything was missing.
How would you know if anything was missing from your CV if you don't have it memorized?
A. I look at the pages to see whether they are in sequence, or anything unusual that I don't put it in my original CV.
Q. Okay. So the pages are numbered like, for example, 1 through 53, correct?
A. 1 to 53.
Q. Is that correct?

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A. Yes.
Q. So in order to determine whether or not there were any pages missing, all you had to do was look at the page numbers at the bottom, instead of running your finger down every publication, isn't that true?
A. I want to make sure --
MS. MILLER: Objection.
Please give me time to object. These questions are objectionable.
THE WITNESS: Okay. Sure.
BY DR. RESTAINO:
Q. Now, you also looked at the document which I believe we've marked as Number 4, which is your study report to determine whether chronic inflammation causes ovarian cancer, correct?
A. This is my report.
Q. And in your report, there's a table that lists each of the 59 slides you have reviewed, correct?
A. You mean which page?

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Q. I don't know the page offhand. But there's a table that you just went through and looked at, correct?
A. You mean the -- these tables?
Q. Yes, sir.
A. Okay. That's what you indicated.
Q. Okay. And when you were checking to see if anything was missing, you ran your finger down every one of those slides, didn't you?
A. I just want to see whether there's any disruption in the number.
Q. Ah. You have those numbers memorized in your head?
A. I know this number, but I don't -- but I don't remember the case ID number for each, because this is the data.
Q. And so how would you know if there was a slide taken out of that?
A. Because there's additions, from 1, 2, 3, 4, 5, to 59, I want to make

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sure if anything missing in between.
Q. Now, sir, have you, in -- in conducting that study --
A. Which study you mean?
Q. Well, yes. Let's -- let's discuss your study report to determine whether chronic inflammation causes ovarian cancer.
A. You mean this report?
Q. Yes, sir. For the -- for -- so that I don't have to name or state that title all day today, would you be comfortable if we referred to that as your study reports?
A. If I'm not clear, I will ask one more time.
Q. Please do. Thank you.
And I will also -- you have also written what we have marked as Exhibit Number 2, an expert report in this litigation, correct?
A. You mean this one?
Q. Yes.
A. Yes. This is my report.

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Q. And I will refer to that with your permission as your expert report?
A. Okay. Again, if I'm not clear I will ask you one more time.
Q. Okay. In the Exhibit Number 1, the notice to produce, we asked for any and all documents that you have that may pertain to scientific or technical publications, written, prepared or presented by you. Number 7 on Page 6.
Do you see that, sir?
A. Yes.
Q. Have you produced those documents?
A. I believe so.
Q. Okay. If you would turn to Page 8 and you see a list of requests there starting with authors of any published scientific studies. And then the second one is the Center For Regulatory Effectiveness.
Do you see that, sir?
A. Yes. B.

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Q. Have -- looking down through those, have you had any communication with any of those organizations listed there that is germane to the talcum powder ovarian cancer litigation?
A. Could you repeat your question one more time?
Q. Looking down through those entities listed there, have you had any communication with any of those organizations that is germane to the talcum powder ovarian cancer litigation?
A. Your communications means personal or?
Q. Personal.
A. Be specific.
Q. E-mail, telephone, snail mail, any -- any communication whatsoever.
A. No.
Q. Now, Number 15 asks for all documents related to research -- I'll wait for you to get there, sir.
A. 14?

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Q. No, not page. Number, request Number 15. It's on Page 11.
A. 11? There's only Page 9.
MS. MILLER: I think you must be looking at the responses and he's looking at the requests. He's -- he's got it.
BY DR. RESTAINO:
Q. Page 9?
A. Are you sure, Page 9?
Q. Yes, Page 9. My apologies, sir.
Number 15 on Page 9.
A. Yes.
Q. All documents related to research, experiments, testing or any other study that's been done or planned by you which you may rely -- rely upon in the talcum powder litigation.
So first, regarding all documents pertaining to experiments that you've performed, you have conducted, as we discussed, and we've called the study report, correct?

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A. So --
MS. MILLER: Objection.
THE WITNESS: So what do you mean testing?
BY DR. RESTAINO:
Q. Well, testing, let's use the definition of looking at histopathological slides.
In that study report, in looking at the histopathological slides, did you produce any and all documents that pertained to that experiment?
A. The documents I produce is the photographs that are shown in my exhibit.
Q. When you were sitting at the microscope looking at a particular histopathological slide, did you take any notes on that slide?
A. No.
Q. Okay. Did you assign that slide a grading system of any sort?
A. What do you mean grading system?

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Q. Well, did you -- if you were looking for the presence or absence of lymphocytes and a particular slide had X number of lymphocytes, did you record that somehow?
A. I used the criteria that practicing pathologists used to diagnose chronic inflammation. So those pathologists do not really quantify lymphocytes. It's part of the very basic training for all board-certified pathologists. So I use the same practice for this study.
Q. Occasionally, during the day I may ask a question that your attorney, to your left, finds objectionable. And she may say objection. That's for the court, and that's lawyer speak. And occasionally during the day, I may say, "Move to strike nonresponsive," which is sort of my side of the table, my way of saying objection. There's no disrespect meant.
I'm going to move to strike

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your previous answer because what I asked you -- and I'll modify it now with what you just said.
Using basic histopathological technique that a board-certified pathologist would use when looking at a histopathological slide for the presence of lymphocytes, did you make any recordation of whether or not there were lymphocytes in that slide?
MS. MILLER: Objection.
THE WITNESS: What do you mean "recordation"?
BY DR. RESTAINO:
Q. Did you write down any notes regarding that particular slide and the presence of lymphocytes?
A. We made the diagnosis based on many informations from the microscopic findings. And we did not write down.
Q. When it was -- when that examination of a particular slide, Slide Number 1, the first one you looked at, if there was no lymphocytes noted on that

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slide -- on that slide, by the time you got to Slide 59, how do you remember what Slide Number 1 was?

A. So the basis is not based on the Case 1 or prior cases. It's based on the knowledge, the training. And I am a pathologist, practicing and doing research for 20 years. And I am the Richard TeLinde distinguished research professor in gynecology pathology, which is probably only one in the professorship in the United States.

And this professorship is regarded as the most premium position in the country. So I trained so many pathologists, and I practice pathologists. I don't need to write down every single details of pathology findings. And we only need what we need, is the final diagnosis. That does matter.

Everything is computing in our brain to come up with the conclusion and the final diagnosis without going to

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any details. Lymphocytes, plasma cells, and, like, NK cells, epithelial cells, and how many blood vessels, how many red blood cells, white blood cells, how many fibroblasts, and how many epithelial cells.

This is not our basis. Our basis is to take into -- take the whole thing into the final decision. Every -- we can consider every aspect and come to our final diagnosis, rather than based on single lymphocytes, endothelial cells, and morphological features.

So basically, I think this is very important for non-pathologists or nonmedical doctors to understand, how do we make the diagnosis of pathology.

So pathology -- what we meant pathology, like, when you have a tumor, whether is it benign or malignant, it's very important, right? You know, your nevus -- could there -- this a melanoma that will kill you, or is it benign nevus, and you are fine?

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So it based on two things. One is architecture of the histology, the relationship between the epithelial cells different, microenvironment, extracellular cells, the architecture, number one.

But it's not sufficient, okay, for the final diagnosis. That is required. The second important thing is cytology. Cytology means the morphological features of the single cells or group of cells.

And we look at the nucleus, if it is benign, or normal, usually they are more homogenous. Okay. It looks very similar to -- to the neighboring cells. But in cancer, in cancer, you will see a lot of different things, we call nuclear --

Q. Sir, I'm going to have to interrupt you now. I'm going to make a motion to strike as unresponsive, because all I asked you is not the technique that a board-certified pathologist may or may

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not use, but when a pathologist is looking at a large number -- God bless you -- large number of slides, and in this case, 59 slides, without recording, making notes of the number, the quantitative analysis of each slide of the number of lymphocytes, how can you remember when you're all done with your analysis, the total number that are present in each slide?

A. Sir, I need to give you the complete and full answer; otherwise, you will not understand how the pathologist made the diagnosis. So if you don't listen to that, you can never understand what your pathology doctor diagnose your tumor or your lesions --

Q. Okay.

A. -- of course, if you had one.

Q. We will discuss that in detail, then, when we get to your study report --

A. Okay.

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Q. -- and go through the methodology that you employed at that time.

Now, Doctor, you were -- you provided deposition testimony in a number of cases involving transvaginal mesh, correct?

A. That's -- I remember.

Q. Okay. And were you an expert at that time for C.R. Bard Incorporated and Ethicon Incorporated?

MS. MILLER: Objection.

THE WITNESS: Could you repeat the companies' names?

BY DR. RESTAINO:

Q. First, C.R. Bard. Does that sound familiar?

A. Okay. How about the other one?

Q. Ethicon.

A. Yes, I remember.

Q. And you were an expert for the defense, correct?

MS. MILLER: Objection.

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THE WITNESS: I was asked as a pathology expert to look at the slides, whether there is any evidence of abnormality on the tissues.

I did not give any opinion outside my pathology expertise.

BY DR. RESTAINO:

Q. Okay. Did you -- in the transvaginal mesh litigation, have you ever testified on behalf of a woman instead of the company?

MS. MILLER: Objection.

THE WITNESS: Could you repeat the question one more time?

BY DR. RESTAINO:

Q. In the transvaginal mesh litigation, were you ever retained as an expert on behalf of one of the plaintiffs, one of the women, complaining of morbidity associated with her mesh?

A. In which case? Bard or --

Q. Either one or any other case. Have you ever -- in the

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transvaginal mesh, did you testify on behalf of any woman?

MS. MILLER: Objection.

THE WITNESS: I testified my pathology findings.

BY DR. RESTAINO:

Q. As an expert for C.R. Bard or Ethicon, correct?

MS. MILLER: I think these are --

THE WITNESS: I think I answer --

MS. MILLER: Objection.

THE WITNESS: -- your question.

MS. MILLER: I think these are legal terms. I think Dr. Shih is a pathologist. Dr. Shih is not a native English speaker. And I don't think it's fair to ask him trick questions.

DR. RESTAINO: We're going to have a nice depo today. We're not going to have speaking

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objections. Those are, "Objection."

BY DR. RESTAINO:

Q. Doctor --

MS. MILLER: No, that is not fair. He obviously doesn't understand your question. And you're purposely trying to trick him. And that's just not appropriate.

BY DR. RESTAINO:

Q. Doctor, have you -- in the transvaginal mesh litigation, were you retained by any lawyer that represents any of the women harmed by transvaginal mesh? Do you understand that question?

MS. MILLER: Objection.

THE WITNESS: I cannot understand the question.

MS. MILLER: Lacks foundation.

BY DR. RESTAINO:

Q. Okay. Did you write expert report as an expert in the transvaginal

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mesh?
A. I report the pathology finding under microscope, whether the tissue has foreign body material or anything that I can show in my report, I report it.
Q. Did you make an analysis of whether that pathology was due to the presence of mesh?
A. I think I defer to clinician for this question.
Q. Okay. When were you first contacted to be an expert in this current litigation, the talcum powder litigation?
A. I think it's in the end December 2018.
Q. And who first contacted you?
A. I think who was Johnson & Johnson attorney firm.
Q. And do you know the name of the lawyer who first contacted you?
A. Who was Jessica.
Q. Okay. Have you worked with Jessica before?

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A. I don't remember.
Q. Did you work with Jessica, for example, in the transvaginal mesh litigation?
A. I did not.
Q. And when you first met with Jessica, what were you asked to do?
MS. MILLER: Objection. Please don't reveal any of our privileged conversations. Any conversation that you and I had is privileged.
BY DR. RESTAINO:
Q. That -- that's a fair objection. Let me strike the question.
I'll represent to you that the expert reports on behalf of the plaintiff, so for example Dr. Sarah Kane, Dr. Saed, those reports were produced to the defense counsel and the courts on -- in mid November of 2018.
Did you see those expert reports in November of 2018?
MS. MILLER: Objection. He

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testified that he didn't talk to me till December.
DR. RESTAINO: Well, we've had some confusion with some answers, so I just want to make sure, from two different ways, that, in fact, he wasn't working for them in November.
BY DR. RESTAINO:
Q. Did you see any expert reports from any of the plaintiffs in November of 2018?
MS. MILLER: Same objection. Mischaracterizes the plaintiff's testimony and further efforts to try to confuse somebody who is not a native English speaker.
BY DR. RESTAINO:
Q. Did you understand my question?
A. Could you repeat one more time?
Q. The expert report of Dr. Sarah Kane, did you see that expert

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report in November of 2018?
A. I first know about this litigation after December.
Q. Now, prior to your deposition today, and prior to being -- to meeting with Jessica, did you ever meet with any plaintiffs' lawyers?
A. Who are the plaintiffs' lawyers?
Q. The defense lawyers are sitting on your side of the table. The lawyers here are the plaintiff lawyers, in addition to others who are not here.
A. I do not remember their faces.
Q. Okay. Do you remember the lovely lady sitting to my right, Michelle Parfitt?
A. I cannot recognize your faces.
MS. PARFITT: I've aged.
THE WITNESS: I hope not.
BY DR. RESTAINO:
Q. Do you recall meeting with

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Ms. Parfitt in 2015?
A. I cannot remember that.
Q. Do you remember having any conversations with a female lawyer in 2015 regarding talcum powder and ovarian cancer?
A. I cannot remember at all.
Q. Do you -- do you recall informing any female attorney in 2015 that in order to render an expert opinion regarding talcum powder and ovarian cancer, you would need to do a rat study?
A. Rat study?
Q. Yes.
A. I cannot remember that either.
Q. Okay. Do you have -- do -- when you meet with lawyers, do you typically charge the lawyers for your time?
A. I think that's correct.
Q. And would you have any record of receiving money from Ms. Parfitt or -- or the law firm

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Ashcraft Gerel in 2015 or -- or 2016?
A. I cannot recall that.
Q. If you did, when you do receive money from attorneys or a law firm for medical/legal consultation, for example now from Johnson & Johnson, does the money go to you directly or does it go to a particular fund at Johns Hopkins or elsewhere?
A. If I receive a check with my name, it come to me.
Q. Would you --
MS. MILLER: And, Michelle, this is all new to us. If there is a conflict issue that you're raising, I -- I submit you should have brought this to our attention many months ago.
MS. PARFITT: We can talk about it off the record. I'm not being examined now. We can talk about it. I need to hear what the doctor has to say.
MS. MILLER: Shall we go off

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the record to talk about it?
MS. SHARKO: Do you want to step out in the hall and you can explain it to me?
MS. PARFITT: No, actually I'd like to continue the deposition. We can take a break at another time. I'd like to continue with the doctor's deposition.
MS. SHARKO: You can go ahead with the deposition, but I think this is kind of unfair. But proceed.
MS. PARFITT: Well, I'm just -- I think when we continue to talk with the doctor, I don't think you'll find anything unfair. The doctor doesn't remember speaking to me. Again, I'm not being examined.
BY DR. RESTAINO:
Q. Dr. Shih, if you checked your checking account or savings account

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for any deposits in 2015 or 2016 from a law firm would you be able to determine that you received money for that consultation?
A. I need to study this.
Q. Okay. Thank you.
Prior to meeting with Jessica in the end of December of 2018 --
MS. MILLER: Objection. He did not testify that he met with me in the end of December of 2018. He testified that I contacted him. That's mischaracterizing the testimony.
BY DR. RESTAINO:
Q. When -- when Jessica contacted you in December of 2018, before you agreed to become -- to -- to work as an expert on behalf of Johnson & Johnson, did you need to approach the Johns Hopkins University ethics department for permission?
A. I don't think there's a guideline for that. I would need to

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report is so-called outside activity. So we report all the outside activity, like consultation and expert witness and we disclose it to our system. And that's it. And I did.

Q. In order to conduct what we have marked as Exhibit Number 4 and agreed to refer to as your study report, did you have to obtain permission from Johns Hopkins University or any other entity to conduct that study?

MS. MILLER: Objection.

THE WITNESS: Can I give you the complete answer?

BY DR. RESTAINO:

Q. It's a yes or no. Did you have to -- did you contact Johns Hopkins University about conducting this study?

A. This study is part of our basic research and our whole team starting from 2012. And this study is in continuation of our 2014, if I can remember correctly, from Ardighieri study published in International Journal of GYN

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Pathology. And this is the continuation of a study. It is not particularly for this litigation, and my opinion is not dependent on this study. And so this study is only part of our ongoing research in answering what is the pathogenesis in initiating high grade ovarian serous carcinoma.

And as you know, there's different types of ovarian cancer. In this study we only focus on, as this chart, I think it's useful for my explanation, is a high grade serous carcinoma. So that is one of our major focus's point.

Q. Okay. This is the Department of Defense grant that you're referring to; is that correct?

A. Correct.

Q. Did you have to obtain permission from anyone involved with that grant to conduct this study?

A. Again, to conduct this study is not for this litigation purpose. It

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just coincidental that we have this research going on. And when I was involved in reviewing the articles and plaintiff material, et cetera, and I feel one of the most important question to be answered is the precursor lesions, which is the -- where the ovarian high grade serous carcinoma originate.

And so this one issue, whether there is chronic inflammation involved in this carcinogenesis of high grade ovarian cancer, is that right? So that is why I think our current study will be able to provide cogent evidence to show or -- or to not show, meaning refute or support.

I don't have any pre-set mind whether chronic inflammation is present in the early precursor ovarian cancer lesions. So that's my purpose.

Q. Sir, you're going to have to ask -- listen to my question carefully and I'll repeat it as -- as many times as you need for me to repair it -- repeat

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it. I'm going to move to strike as unresponsive because my question, sir, was did you have to obtain permission from anyone that -- involved in that grant in order to conduct what you just described as a continuing study from that grant?

A. So as a scientist, we publish papers. We don't need to report every time to the grant -- grant agency, NIH or DOD, to afford permission. This is the freedom of academia.

Q. Okay. And that grant involves millions of dollars, does it not?

A. For many investigators and many institutions.

Q. Now, for the time that you spent developing the methodology that you were going to employ to do the study, for the time spent looking at -- looking at the histopathological slides, for the time spent writing your study report, are you billing the grant for that time?

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A. The grant has expired, okay. So my research on this is supported by my own time.
Q. Are you -- did you bill or will you bill anyone representing Johnson & Johnson for the time you spent developing the methodology for the study, reviewing the histopathological slides, and writing your expert report?
A. I will not.
Q. So all of that time that you've spent, you will not be reimbursed for -- from anyone for that time; is that correct?
A. Anyone means?
Q. Any -- the university, any other grant money, any other entity. Will anybody be paying you for that time that you spent?
A. Sir, you need to understand, when we do a research, every research, okay, there's many publications. We report it. We did not charge each publication to any agency, no, we are

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not. We are paid by the fixed salary to do this, to do all the academic research, education, clinical practice, and administration.
This is just part of the academia success in the United States. You cannot break into every single one.
For example, I interview with a faculty. I charge the institution. We did not do it that way. So this is totally different for other business.
In academia -- let me finish. This is very important. We are the scientists. We are here to do education, clinical practice, research for the benefit of all the women in whole wide world for ovarian cancer.
Q. Sir, again, I have to interrupt you. I'm going to move to strike as unresponsive. My simple question is, are you billing anyone for the time you spent designing, conducting, and writing up your report from that

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study?
MS. MILLER: Objection. Asked and answered.
He said he wasn't.
THE WITNESS: I did answer your question very clearly.
BY DR. RESTAINO:
Q. Your answer is no?
A. I already answered your question.
Q. Okay. Sir, do you consider yourself an expert in epidemiology?
A. I am a cancer biologist who focus on -- I understand what initiate ovarian cancer, and I am also practicing gynecology pathologist. And I also run -- educator to train residents, pathology residents, post-doc fellows, and the graduate students in ovarian cancer research and diagnosis.
Q. Do you have expertise in epidemiology?
A. As a scientist, I always review epidemiology literatures. It's

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part of my background to study it, the issue. And also it's in my context.
So you cannot say a scientist only focus on biology without knowing the other fields. I don't think it will work. Any great scientist shall not do that. They should review all the literatures related.
Q. I'm sorry, sir.
A. Sorry.
Q. And by reviewing the published literature dealing with epidemiology, does that give you expertise in epidemiology?
MS. MILLER: Objection.
THE WITNESS: As I said, I reviewed other literatures in order to know better about the issues, about the -- what is the origin of ovarian cancer.
And it is a background in my study and also in my context.
BY DR. RESTAINO:
Q. Okay. Do you have expertise

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in toxicology?
A. Again, I'm a cancer biologist and gynecology pathologist.
Q. Okay. Do you have expert -- expertise in mineralogy?
A. How do you define mineralogy?
Q. How would you define mineralogy?
MS. MILLER: Objection.
THE WITNESS: Because I can't understand your word. Could you explain that.
BY DR. RESTAINO:
Q. The study of minerals, for example talc and asbestos.
A. Ah.
Q. Are you an expert?
A. No, I am not.
Q. Do you consider you're an expert in talcum powder products?
MS. MILLER: Objection.
THE WITNESS: Could you be more specific for the question?

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BY DR. RESTAINO:
Q. Are you familiar with talcum powder products?
MS. MILLER: Objection.
THE WITNESS: What do you mean familiar with?
BY DR. RESTAINO:
Q. Do you know what is in, for example, bottles of Johnson & Johnson talcum powder?
A. I think you have several questions in a stream. Could you -- might go by steps, your question, one by one by one, so I can answer your question more effectively.
Q. Do you know what the constituent parts of Johnson & Johnson's talcum powder is or are?
A. You mean the Johnson & Johnson's powder in the market?
Q. Yes.
A. Or in -- back to ten years ago, 20 years ago, 30 years ago? What do you mean?

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Q. Today.
A. Today, I did not see any Johnson & Johnson's powder.
Q. Okay. Have you heard of Sir Austin Bradford Hill?
A. Could you spell the name correctly?
Q. Sir Austin Bradford Hill. Have you heard of him?
A. I saw -- I know the documents -- I know the documents. Okay. Through this kind of expert opinion, investigation, and I -- I remember I saw that document, but I cannot remember any single word.
Q. Did you conduct an analysis in this case utilizing the Bradford Hill viewpoints on causation?
A. Again, can I have this Brad Hill -- Bradford Hill documents before we can further discuss?
Q. I'm not sure what you mean by the Bradford Hill documents. But do you recall reading at any time in your

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professional career a 1965 publication by Sir Bradford Hill regarding viewpoints for determining causation?
A. Can I see the viewpoints for our discussion?
Q. I just want to know if you recall seeing that paper.
A. I need to see the paper in order to answer your question.
Q. Do you recall anytime reading a published paper dealing with causation and viewpoints that consisted of, for example, the strength of association, analogy, biological gradient, biological plausibility, analogy, experimentation, and coherence? Do you recall ever seeing any document like that?
MS. MILLER: Objection. Compound.
THE WITNESS: I need to see the documents before we can further discuss.
BY DR. RESTAINO:

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Q. Without seeing any document, you can't recall ever reading or seeing a study or publication dealing with viewpoints of causation?
A. I saw the viewpoint, but I need to see documents to see which ones specifically you refer.
Q. When you were doing your analysis of the published literature and your study report to make a determination as to whether or not the Johnson & Johnson's talcum powder products were associated with any form of ovarian cancer, did you go through a list of viewpoints to determine whether the association was causal?
MS. MILLER: Objection. You -- you --
DR. RESTAINO: Objection works.
MS. MILLER: There's no foundation. This mischaracterizes his testimony. These questions are really not fair.

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When did he say that he did an analysis of the published literature and a study report to make a determination as to whether not Johnson & Johnson's talcum powders were associated with any ovarian -- form of ovarian cancer?
I'm sorry to be giving speaking objections, but as I said, this gentleman is a scientist. He is not a native English speaker, and I think the questions should be fair.
DR. RESTAINO: Your objection is noted. Let's keep it to objection. They are the federal rules.
MS. MILLER: I'll say objection unless I feel that the question is stated in such a way that it is intended to mislead this witness.
DR. RESTAINO: Actually you're going to keep it to

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objection or we're going to call the judge.
MS. SHARKO: Okay.
DR. RESTAINO: We can fight about it over another time. I'm trying to be clear as I can for someone whose English is a second language. I know that and I respect it.
BY DR. RESTAINO:
Q. Doctor --
MS. MILLER: Your question embedded an entire assumption that had never been made in this deposition, that had never been accepted by the witness. And I think that's hard for somebody to understand who doesn't -- who is not -- English -- who does not speak English as a first language.
So I'm just asking to please keep the questions to straightforward questions that don't embed false assumptions.

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BY DR. RESTAINO:
Q. Doctor, if you would turn in your expert report which is marked as Exhibit Number 2 and turn to Page 11. And now, there's a figure there. Figure Number 2 on Page 11, correct?
A. Correct.
Q. And right above that, there's a sentence where you write, "Without this direct molecular pathology evidence," do you see where I am, sir?
A. I'm sorry, where are you?
Q. The sentence right above the figure.
A. Okay. Okay. I saw it.
Q. "Without this direct molecular pathology evidence, a causal relationship of talc and ovarian cancer cannot be established (see below)."
Do you see that, sir?
A. Let me finish the whole section, okay.
Q. No, sir. I just want to know if you -- if you can see that

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sentence that I just read.
A. Okay.
Q. Do you see that, sir?
MS. SHARKO: He's just directing your attention to that sentence.
THE WITNESS: Oh, okay, yeah, I saw the sentence you --
BY DR. RESTAINO:
Q. You see the sentence.
A. -- you mentioned.
Q. And it is your expert opinion, is it not, that without direct molecular pathology evidence, a causal relationship of talc and ovarian cancer cannot be established; is that correct?
A. I think any cancer biologist will agree that you need to see the genetic mutation in order to establish causal relationship. As you know, the cancer biology, cancer origin is based on genetics, and cancer is a genetic disease. It must have mutations. There's a difference between cancer and

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normal cells.
So in order to understand the sentence I wrote, you need to understand that cancer is just not coming from nowhere. It has a basis of molecular genetic changes, including somatic mutations in cancer driver genes, which is in contrast to cancer mutational genes. And the cell, this is the origin that every cancer can -- can develop. Without mutations, there's no way that you can say that this is the -- the causal.
Q. Okay. So is it your expert opinion that before a causal relationship between an environmental agent and cancer can be established, you have to see evidence of direct molecular pathology?
MS. MILLER: Objection. Mischaracterizes the witness's testimony.
THE WITNESS: What I said is you need to have cogent evidence and credible science and

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methodology to support biological plausibility and the mechanism. And mutation is one of them, is one of them.
BY DR. RESTAINO:
Q. Do you recall in any of your readings the statement that -- regarding biological plausibility? Are you familiar with that term?
A. Could you define your definition? I don't know which biological plausibility you refer to.
Q. I'm not referring to any specific form of biological plausibility. You as an expert, can you define for us what is meant by biological plausibility?
A. Okay. In my opinion, biological plausibility is the evidence, based on very good methodology, that can support a statement. For example, talc is causal to ovarian cancer.
Q. And is it biologically plausible in your mind as an expert that talc, talcum powder, is associated with

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ovarian cancer?
MS. MILLER: Objection. He said causal, you're saying association.
THE WITNESS: I said causal. You say association. I don't mean association.
Association doesn't mean it's causal. It is a very basic scientific logic, everybody should know that.
BY DR. RESTAINO:
Q. Would you -- do you agree that the biological plausibility depends upon the science of the day, would you agree?
A. That's too general. I cannot answer that. If you have more specific, give me an example, then I can give you an answer.
Q. Would you agree that science is a continuum and what scientists know one year from now might be different from what scientists know today?

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A. It depends on what kind of science. Only true science will survive.
Q. Okay. Would you -- do you agree that research is never finished, but carries on and on?
MS. MILLER: Objection.
THE WITNESS: This is too general. I don't know what this means.
MS. MILLER: Doctor, please remember to give me ten seconds --
THE WITNESS: Okay.
MS. MILLER: -- between his question and your answer so that I can lodge my objection and the record is clear.
BY DR. RESTAINO:
Q. And I'm sorry, regarding research, would you agree that research never is finished?
MS. MILLER: Objection. Vague.
THE WITNESS: Is too vague a question. I cannot answer that.

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BY DR. RESTAINO:
Q. You don't understand what I mean by asking --
A. It's too vague. It's not -- I cannot understand.
Q. Are you familiar -- familiar with basic epidemiological principles?
A. What do you mean basic principle? It's too general.
Q. Do you know how, when looking at a study that has some degree of epidemiology in it, do you know how to interpret a confidence interval?
A. Again, I'm a cancer biologist and a gynecology pathologist. I review those articles that is relevant and important and -- and related. I am not epidemiology expert. You can -- you should defer those question to them. I can -- I am here -- okay. This is very important.
My job here is served as an expert in cancer biology and gynecology pathology to answer whether talc is -- is

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causal or not.
Q. And you looked, did you not, at various epidemiological studies looking at the association of talcum powder and ovarian cancer, correct?
A. I study some of them.
Q. In fact, if you look in your expert report on Page 11?
A. Yes, I saw it.
Q. Okay. Are you on Page 11?
A. Yes, I am -- I think so.
Q. Do you see there on -- on Page 11 a description of epidemiological studies that you reviewed?
A. Which -- which line you are talking about? Which study? Could you name the first author of the study and year?
Q. On the -- on the bottom of Page 11, you have a numbered paragraph, Number 4, correct?
A. Yes.
Q. Do you see there where you've written, "A number of

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epidemiological studies clearly fail to show an association between talc exposure and women who develop ovarian cancer including prospective cohort studies (Houghton, et al., 2014; Gertig, et al., 2000; Gates, et al., 2010; Gonzalez et al., 2016)?"
Do you see that, sir?
A. Yes, I did.
Q. Now, you reviewed those studies?
A. I reviewed the study quickly and come to my report. But I -- I should say I reviewed those articles and not only these four, but several here. So I just come up with my general opinion as a sum, as a cancer biological view, like a bird's-eye-view about epidemiology. I cannot give you the full-blown -- and the details about a specific study.
So what I feel after I review this, Gertig, Gates, Gonzalez, Houghton, and several others perhaps, my thinking is number one, those

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epidemiology studies did not show consistent result. For example, as you know, there are two basic epidemiology studies. One is longitudinal cohort -- okay, cohort.

MS. SHARKO: Dr. Shih, I'm going to interrupt you to help Mr. -- Dr. Restaino out. He just wants to know if you looked at those studies. And so --

THE WITNESS: Okay. Thank you very much.

DR. RESTAINO: Thank you.

MS. SHARKO: That's his question. Then he's going to ask you another question.

THE WITNESS: Okay. Yes, I reviewed those studies.

BY DR. RESTAINO:

Q. When you --

MS. MILLER: Is this -- oh, sorry.

DR. RESTAINO: I'm sorry. Go ahead.

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MS. MILLER: I think we've gone an hour. I think we could all use a bathroom break. Is this a good time?

DR. RESTAINO: This is a good time.

THE VIDEOGRAPHER: The time is 10:09 a.m., and we are going off the record.

(Short break.)

THE VIDEOGRAPHER: The time is 10:24 a.m. We are back on the record.

BY DR. RESTAINO:

Q. Welcome back, Doctor.

A. Thank you.

Q. When we broke and we were talking about your review of the different epidemiological studies. And I believe you said that your view of this was a bird's-eye-view; is that correct?

A. I summarized what I studied from this literature.

Q. As far as the strengths and

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weaknesses of each epidemiological study, would you defer to someone who has expertise and a degree in epidemiology?

MR. LOCKE: Objection to form.

MS. MILLER: Objection.

THE WITNESS: If the strength is really high, like a 20, 30, like cigarette smoking, I think everybody will accept that's a risk factor.

If really low, like 1.5, below, 1.1, it could be just by chance and that's needed expert -- experts to look into that to study the confounding factors, case number and et cetera, et cetera.

BY DR. RESTAINO:

Q. When you are writing an academic paper for publication, any paper, do you typically conduct a review of the literature for articles germane to the paper you were going to write?

A. I will cite many papers that

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are relevant to my study, but will not be able to comprehensively list all the literatures.

Q. How do you determine what is all of the literature?

A. You can go to PubMed search or Google Scholar search about the keywords that you have an interest and related to that specific studies.

Q. Did you do that before you wrote your expert report in this litigation?

A. Yes, I did.

Q. And can -- as you sit here today, can you recall and share with us some of the keywords that you used?

A. Okay. If I can remember I will let you know, okay.

One is talc, talcum powder, ovarian cancer -- could I go slowly -- pathogenesis, tumor initiation, TP53 -- that's a gene name -- high grade serous carcinoma, and of course ovarian cancer.

Q. Okay. Do you know the

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difference when conducting a review of the literature between a systematic review of the literature and a narrative review of the literature?
MS. MILLER: Objection.
THE WITNESS: I think that's too general a question, could you become more specific?
BY DR. RESTAINO:
Q. Yes, sir. Have you heard of the term "systematic review of the literature"?
A. The system review of literature is what I did. That's my definition, looked into the search engine, like Google Scholar and PubMed and put in the keywords. Then you will come out with a list of article, right? So then, I scan quickly, the authors, the titles, and to determine whether this is relevant, either by looking at titles and the authors. If I decide it is an interesting one, I will read more carefully.

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Q. Do you know what is meant by the term "narrative review of the literature"?
MS. MILLER: Objection.
THE WITNESS: Does that mean review -- read review articles?
BY DR. RESTAINO:
Q. Yes.
A. Okay. That's what you meant?
Q. Yes.
A. I did that also too occasionally, if this is germane to my study and is useful for the paper.
Q. Did you -- and I know it's not a memory test, did you use the keyword "inflammation" when you were doing your search of PubMed, Google Scholar, and whatever database?
A. Yes, I believe so.
Q. Okay. And you reviewed the expert report of Dr. Sarah Kane, correct?
A. I think I was provided with Saed's report.

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Q. And you were also provided with the report of Dr. Sarah Kane, which you describe in your expert report; is that true, sir?
A. I cannot remember that.
Q. Do you remember reviewing an expert report of a gynecologic pathologist from up in Boston?
A. Oh, yes.
Q. Do you recall reviewing the methodology that she used to write her expert report?
A. I know she report pathology, methodology, but I need to have the documents before I can further discuss.
Q. Okay. Do you know as you sit here today, if she conducted a systematic review of the literature and then wrote her expert report?
A. I don't know.
Q. Do you know as you sit here today, if you disagree with the methodology that Dr. Sarah Kane utilized to write her expert report?

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A. I need to see the report first. I cannot recall at this moment.
Q. Okay. Do you recall reading Dr. Saed's expert report?
A. Yes, I recall it.
Q. And you have criticisms of the methodology he employed to write his expert report?
A. Yes. And this is in my expert reports shown in Exhibit 2.
Q. Yes, sir. Thank you.
A. Yeah, here.
Q. Now, in -- I believe it's expert -- excuse me -- Exhibit 4, your study report. It's titled "Study Report to Determine Whether Chronic Inflammation Causes Ovarian Cancer."
Do you have that, sir?
A. Yes.
Q. Now, you are the sole author listed on the version that we were provided; is that true?
A. Correct.
Q. And will there be other

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authors -- strike that. I'm sorry.
Doctor, do you plan on submitting this publication for peer review and publication?
A. Yes.
Q. Have you submitted it already?
A. Not yet.
Q. The -- as you sit here today, do you know if the version that you submit for peer review and publication will have co-authors with you?
A. I have no plan yet what kind of other data will be included. So I cannot answer the question for the future tense.
Q. Is it fair to say then that your study report as provided today is an unfinished product?
A. It is an ongoing project.
Q. Have you discussed the methodology that you used with this report with any other investigator at

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Johns Hopkins University?
A. No.
Q. Did you study the -- did you discuss the methodology that you would use for your study report with any representative of Johnson & Johnson?
A. No.
Q. Did you discuss the methodology that you would use for your study report with any scientist that's -- or physician not with Johnson & Johnson and not with Johns Hopkins?
A. Could you repeat that question one more time?
Q. Did you discuss your methodology with anyone else other than a scientist from Johnson & Johnson or a representative from Johnson & Johnson or physician/scientist from Johns Hopkins?
A. As I said, this is my own study.
Q. I appreciate that -- that it's your own study. But in discussing how to do the study and how to best glean

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the truth from your study, did you discuss the study methodology for example, with Dr. Kurman?
MS. MILLER: Objection. You said in discussing how to do the study, but he said he didn't discuss the study. So I'm confused by the question.
THE WITNESS: Yeah, I think I answered your question already.
BY DR. RESTAINO:
Q. Prior to writing your study report, did you discuss what you were doing with Dr. Kurman?
A. No.
Q. Has Dr. Kurman, to the best of your knowledge, seen the version of the study report that we have at this time?
A. I don't know whether he see it or not.
Q. Now, if you -- on the first page of your study report, underneath your name and your address, there's time

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frame, January 1st, 2019, to February 11, 2019; is that correct?
A. This time frame was generated based on when I draft this report, and I think I can finish between January 1st to February 11, 2019. That's my projection.
Q. In any period of time between January 1st and today, did you share any drafts of your study report with anyone?
A. Anyone means?
Q. Anyone but you. Has anyone else seen any drafts of your study report?
A. I think it's included in this exhibit, so everybody now see it.
Q. Okay. Prior to today, and prior to it being distributed amongst the attorneys, did you share any drafts of that report with anyone?
A. I did not share it with any of my colleague scientists --
Q. Okay.

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A. -- and any other colleagues near -- near me.
Q. Did you share any draft of the study report with any representative of Johnson & Johnson?
A. You mean a draft, no.
Q. Okay. Are there drafts of your study report?
A. There is no draft.
Q. And when you first sat down and thought about what study you would like to do, to look at the question regarding chronic inflammation and ovarian cancer precursor cells, did you write up a protocol for yourself?
A. What do you mean protocol?
Q. Did you write down a plan for how you anticipated conducting the study?
A. No.
Q. Now, for your histological analysis, you identified cases that were showing ovarian cancer precursor lesions without concurrent ovarian cancer; is

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that correct?
A. Yes. But which page are you referring to now?
Q. I'm just asking in a general sense.
A. Yes.
Q. Okay. And then you also selected some cases with ovarian cancer as control; is that correct?
A. I -- you must refer to the table, yes.
Q. Okay. Now, how did you identify the cases that had ovarian cancer precursor lesions without concurrent ovarian cancer? Were the slides labeled?
A. No. It's based on the pathology reports and my re-review of the slides.
Q. Who wrote the pathology reports that pertain to each specific slide?
A. The individual pathologist who diagnosed that case. And I

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re-reviewed the whole material before I conducted this study and write down my results as shown in the table.
Q. So if you wanted to see the slide that had evidence of p53 signature lesions, was there a list of those slides that had that pathology?
A. I think that's correct. But I need to re-review -- re-review them. Sometimes they are not present anymore for study because they are very small and minute.
Q. I'm sorry, sir, what are small and minute?
A. So could you go back to this Figure 2 so I can explain to you what this minute means.
Table 2 in my report.
Q. The listing of your 59 slides?
A. No, no, no, not that one. This one.
MS. MILLER: He's talking about his report. I think.

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DR. RESTAINO: Oh, I'm sorry. Forgive me.
THE WITNESS: Oh this one here. Page 11 here.
BY DR. RESTAINO:
Q. Yes, sir.
A. So you need to understand this precursor lesions are very small.
Q. I understand precursor lesions --
A. Okay.
Q. -- probably more than I want to.
My question is, sir, if you were going to determine if there were lymphocytes associated or -- or listed in a particular slide with p53 lesions in it, was there a list of the -- of the slides that already had p53 lesions or did you have to go through every slide to find them?
A. I think your question has two parts. One is p53 signatures, whether this is listed?

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Q. Yes.
A. Okay. I think it is listed. But I need to re-review them.
Q. Okay.
A. Okay.
Q. Okay. And then also --
A. Second question, chronic inflammation.
Q. Okay. Now -- but can the same thing be said for the --
DR. RESTAINO: Excuse me. God bless you.
MS. SHARKO: Thanks.
BY DR. RESTAINO:
Q. Regarding other pathology, in other words, you looked at the p53 signature lesions and you also looked at the serous tubal intraepithelial cells, correct?
A. Yeah, very good.
Q. Can we call them STIC?
A. Please.
Q. Okay. Did you -- is there a listing in the data bank where you

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obtained these slides of the slides with STIC lesions in them?
A. This would be really complicated to answer, because basically I need to retrieve the slides and I need to re-review all of them to make the diagnosis. So I will say the diagnosis, this -- in this table is based on my review of all the cases, is my own diagnosis.
Q. Okay. With that table open in front of you, sir, if you took at lesion Number 1, the very top one?
A. Yes.
Q. Case ID S8001 diagnosis p53 SIG, does that stand for signature lesion?
A. Yes.
Q. Okay. Now, did -- did you take out slide -- or excuse me, Lesion 1, slide S8001, 8001, and did you make the diagnosis of p53 signature lesion or was there a listing of slides that said, if you want to see p53 signature lesion,

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look at this slide?
A. Okay. I get you. So I made a diagnosis of p53 signature by myself in this study.
Q. Thank you.
Okay. So how many slides are in the data bank that you --
A. I don't know. I need to -- I don't know that number.
Q. How did you derive or decide upon which 59 slides that you were going to look at?
A. I looked at those slides with the lesions, and they are available for me to review.
Q. But how did you know which slides had which lesions to pull them?
A. Okay. So your question is, how can I select those cases, right?
Q. Yes, sir.
A. Okay. So, basically, this study we collect all the tubal lesions, including p53 signatures and STIC from the pool of cases. Then we combine them

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into our study.
So in order to know exactly is a p53 signature STIC or there is no lesion anymore, or there's a cancer, I need to review every single case of that.
Q. So for Slide Number 1, Case ID S80001, when you sat down at the microscope, you knew that someone had already diagnosed p53 signature lesions in that slide; is that correct?
A. I think this cohort -- not cohort -- collection, labels, tubal lesions, including p53 signature and STIC. And sometimes they have STICs and p53 signature and cancer or without cancer. So it's really complicated. It's not only p53 signature.
This pool that I -- we just talking about is the collection of all tubal lesions. It's really vague. It's just labeled positive. Then I need to diagnose and confirm the diagnosis before I conduct these experiments.
Q. Okay. If you would turn to,

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in your full study, on Page 1, you have a paragraph that you have titled "Hypothesis"; is that correct?
A. Correct.
Q. And if you look down five lines, sir, in the middle of that paragraph, towards the right of the paragraph, there's a sentence that starts, "We hypothesize that if ovarian cancer."
Do you see that, sir?
A. Oh, okay. Yes.
Q. If you're the sole author, who is the "we"?
A. Okay. So, let me see this. I will actually explain to you. So in scientific community, we always use "we." So this is engrained into my brain. I never say I, because we are not so arrogant. Scientists is always very poor people.
MS. MILLER: Sorry to laugh at you.
THE WITNESS: We try to test

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all the hypothesis, many hypothesis, but all failed.
BY DR. RESTAINO:
Q. Okay.
A. So it's really --
Q. I was just trying to confirm, sir, if you did --
A. Yeah.
Q. -- this alone or if there were others.
A. Of course. Of course. Of course.
Q. Now, under study design, on the next page, you have a paragraph titled "Study Design and Case Selection," correct?
A. Yes.
Q. And you write, "The cases were retrieved from the archival files from the ovarian cancer precursor registry supported by U.S. Department of Defense (USA MRMC) directed medical research programs (CDMRP) grant title 'Prevention of Ovarian High Grade Serous

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Carcinoma by elucidating Its Early Changes,' Grant Number W81XWH-11-2-0230."
Did I read that correctly, sir?
A. Yes.
Q. Now, that's an -- that was the ongoing grant that you have many publications for; is that correct?
A. This grant has ended.
Q. Okay. There's no more money to be obtained from that grant?
A. I wish, but no.
Q. Now, associated with this grant, the slides that were available for you to review, are they located at the Johns Hopkins University slide bank, or did you have to go to another university to get them?
A. It's inside of Johns Hopkins research building, and this is a government funded, so we are responsible to take care of them.
Q. Okay. And associated with each slide, is there a medical history of

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the woman from whom the tissue was obtained?
A. I cannot recall that, because it's under the IRB regulations, so that's -- I cannot remember correctly what IRB said.
Q. And in fact, in several of the publications that you have published or co-authored that involves a histopathological analysis of the slides from this grant that we just discussed, you list that you obtained internal review board approval, correct?
A. Correct.
Q. Did you obtain -- oh, excuse me. Internal review board. Would it be okay if for the rest of the day, we just say IRB?
A. I agree.
Q. You're familiar with IRB?
A. That's why we did study.
Q. Okay. Did you obtain IRB approval to conduct the study that we are discussing today?

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A. I think every time DOD give the fund, they need to approve every regulatory documents.
MS. SHARKO: Dr. Shih, he's just asking you, if to do this slide review that you did, you first got IRB approval.
THE WITNESS: Yes. And this is required.
BY DR. RESTAINO:
Q. For this study that we're discussing today, the -- the appropriate IRB gave you approval to do the study?
A. Yes. This -- okay. So this study, the IRB in the original form, and actually the IRB continues, okay, even the grant expired, because IRB is defined as the study, not dependent on whether we have it funded or not. It's only research oriented.
So we obtain the IRB in the very beginning for many, many years, and so it's include different kinds of studies.

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Q. So, is it your testimony that you did not need specific IRB approval to pull these 59 slides and look at them?
A. In fact, I submit addendum of the IRB report, including to investigate chronic inflammation in the precursor lesion, and the microenvironment, epigenetic study, and to many other things.
Q. And to whom did you submit the addendum?
A. To the Johns Hopkins eIRB.
Q. And when did you do that?
A. I cannot recall.
Q. Prior to conducting this study?
A. Again, as I said, this study about the chronic inflammation and the microenvironment was ongoing for many years. And as you can see, there's Ardighieri publication, 2014, in the International Journal of GYN Pathology, and this is in continuation.

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Q. You do not -- or do you state in the study report anywhere that IRB approval was obtained?
A. Could you repeat the question one more time?
Q. Can you show us in the study report that you have in front of you where you state that IRB approval was obtained?
MS. MILLER: Objection. Lacks foundation.
MS. SHARKO: He wants to know if, looking at your report, you refer anywhere to getting IRB approval.
BY DR. RESTAINO:
Q. Do you understand what I mean, sir?
A. I did not recall I put that in, but in future publication, definitely I will put that in.
Q. Okay. In your -- in the version of the study report that we have, can you show me where you discuss the

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limitations of your study?
A. This is the data I want to show to you guys today. But the limitation, definitely I will say that in my publications. And actually in -- I think I put the limitation in more speculated terminology in my study reports, based on my publication records. This is very different from some very sloppy bench science publication, without acknowledge any of the limitation.
Q. As you sit here today, do you know if you've ever published a paper pertaining to a study wherein you did not describe the limitations of the study?
A. The limitation depends on how you present it. It can become speculative. It is possible. And further study is required. So the limitation, the term may not be used by the implication of the limitations exercise in the report.
Q. Do you -- I'm sorry, sir. I did not mean to step on your sentence.

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In the version of the study report that was provided to us, can you show us where you describe the limitations of your study?
MS. MILLER: Objection. He said earlier that --
THE WITNESS: I did answer your question.
BY DR. RESTAINO:
Q. Is the word "limitations" to be found anywhere in this -- in the version of the report that we've been provided with?
A. Again, this is ongoing projects, ongoing results, it is by no means that this will be the final publication report. And of course we have not written the paper yet, but when we -- when I -- I am sorry. When I finish this study and try to publish it and when I draft the manuscript, definitely like in other publication I did, I will use the term to show the limitation, but not necessarily using the

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term, the word of limitation in the study outcome.
Q. Sir, if you would turn now to your expert report instead of the study report, but your expert --
A. Expert report.
Q. Your expert report, please. And -- and turn to Page 16 of your expert report.
Do you see, sir, the first full paragraph at the top which starts, "In reality," --
MS. MILLER: Page?
THE WITNESS: Page 16?
MS. MILLER: I don't have that on Page 16.
DR. RESTAINO: It may not be Page 16.
Page 15, forgive me.
BY DR. RESTAINO:
Q. Page 15. Do you see the paragraph up above, it starts, "In reality, chronic inflammation."
Do you see where I am, sir?

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A. Yes.
Q. Now, the second sentence states, "My recent study, which is included in full at the end of this report, offers significant support for this conclusion."
Did I read that correctly?
A. Yes.
Q. Is it your testimony today that the -- your recent study we've been discussing is not the full report but is going to be modified?
MS. MILLER: Objection.
THE WITNESS: This is the data I have, but when you wrap up a study, you have other ingredients, like introduction, methodologies, result, discussion.
This is not full report as a publication. I mean a full report meaning it's publication. Okay.
But this is a full result I have at this moment.
BY DR. RESTAINO:

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Q. A moment ago you testified that it could change, your opinions could change. You state, again, this is ongoing projects, ongoing results.
A. Yes.
Q. So, is it fair to say that your opinions in your expert report, in the study report that you've provided to us and that you are providing today, are preliminary results?
MS. MILLER: Objection.
THE WITNESS: Could you repeat the question? I think there's two questions in your previous statement. Could you break it up?
BY DR. RESTAINO:
Q. You stated that there were ongoing results. So if there's ongoing results --
A. No.
Q. -- is it --
A. It is ongoing study, not results.

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Q. Okay. And so that there isn't any confusion, particularly on my part, sir, I want to give you what's been marked as Exhibit 27 I believe.

(Document marked for identification as Exhibit Shih-27.)

BY DR. RESTAINO:

Q. And do you recognize that paper, sir?

A. Yes, I recognize it.

Q. Okay. If -- if you turn to Page 6546. Okay, sir? Are you there?

A. Yeah.

Q. Do you see there's a section titled "Acknowledgments"?

A. Yes.

Q. And do you see that they -- that there is written there, "The work was supported by the Honorable Tina Brozman, B-R-O-Z-M-A-N, Foundation and the Department of Defense CDMRP," and then there's the grant number that we discussed earlier. That's the same grant

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that we have been discussing; is that correct?

A. I think so.

Q. And were the materials that were utilized for this study, "Methylomic analysis of ovarian cancers identifies tumor-specific alterations readily detectable in early precursor lesions," obtained from the same Johns Hopkins University tissue or slide bank as your present study?

A. Could you indicate where is the sentences?

Q. I was -- put your attention to the acknowledgments. Do you see under acknowledgments?

MS. MILLER: Do you want me to show him?

DR. RESTAINO: Sure. Thank you.

THE WITNESS: Yeah, I saw that acknowledgement.

BY DR. RESTAINO:

Q. Okay. And you see that the

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grant number is listed there, correct?

A. Correct.

Q. And that's the same grant that we've been talking about so far this morning?

A. This is only one of the grants with acknowledgments.

Q. Okay. And I just wanted -- for the record, it's the same grant?

A. Yes.

Q. Now, for the slides for this paper, the methylomic analysis, were they obtained from the same Johns Hopkins tissue bank?

A. They are obtained from different resources within Johns Hopkins.

Q. Okay. Now, if you would turn to Page 6537 of that article. And you'll see there that there is a materials and methods section.

A. Right.

Q. And the first full sentence of that section, it is written, "This study was performed after approval by

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Institutional Review Board (IRB) and conducted in accordance with the U.S. Common Rule."

Do you see where I read that from, sir?

A. Yes.

Q. Will your final paper, your study report that when it's submitted for publication, will that contain that similar language?

MS. MILLER: Objection.

THE WITNESS: It will.

BY DR. RESTAINO:

Q. But it does not at this time, correct?

A. It's not a paper yet. We have not -- I have -- I'm sorry, excuse me as a scientist. We are teamwork.

I did not submit the paper yet. I did not write the paper yet.

Q. So what is it that we are looking at when we see the full study report, as you describe it, what is that?

A. Excuse me, what, could you

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repeat one more time?
Q. Exhibit 4, your -- the study itself.
A. Yeah.
Q. What you describe as being attached in full to your expert report, if it's not a paper yet, what are we -- is it, what are we looking at, sir?
A. It's interim report to show that -- to address one of the most important questions regarding whether talc will cause inflammation, inflammation will cause precursor lesion where ovarian cancer originate from.
Q. But your expert report describes it as a full report. Is it a full report as in your expert report or is it an interim report as you just stated?
A. Which were you -- which -- which one are you talking about? I'm confused.
Q. The study report.
A. Okay. My study report.

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This one?
Q. Yes.
A. And where --
Q. Is that a full report or is it an interim report? It's Exhibit 4. It should be marked as Exhibit 4.
A. Yeah, right.
This is the full report at this moment.
Q. Okay. Going back to the paper we just handed to you, the methylomic paper, and if you turn to Page 6545.
Are you there, sir?
A. Yeah.
Q. There's a large paragraph, right column down towards the bottom that starts, "There are a number of limitations to our study."
Do you see that, sir?
A. Yes.
Q. Okay. I'll read it in full.
"There are a number of limitations to our study that warrant

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consideration."
Do you have that language in the full interim report that you have provided to us?
MS. MILLER: Objection.
THE WITNESS: I think I answered your question already. I think in the final publication we prepared, I will do that.
And this is my style. In every paper I will be sure this will be included.
BY DR. RESTAINO:
Q. Thank you, sir. I understand.
As you sit here today, can you share with us any of the limitations that exist regarding the study you conducted that we've been discussing?
A. Could you repeat one more time and more specific, what do you want me to do?
Q. Yes.
A. Okay.

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Q. Thank you, sir.
What are the limitations of your study as you've performed it?
A. In this Exhibit 4?
Q. Yes, sir.
A. Okay. So I think you are asking me if I have -- if I wrote or write the publication or manuscript, including this result, what shall I say, right?
Q. Yes.
A. So when a scientist write a paper -- so for example, I am going to write this paper, it depends what kind of data I want to include. So this will be part of it, and it will join other data, which we don't know, to come up with the best publication to submit at very high impact journal. That's our purpose.
So at this moment, we don't -- I'm sorry, I don't know whether this will be a single long paper just reporting this finding or in combination with other finding as multiple reports or

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a single one publication report. I have no idea yet.
Q. But as you sit here today, can you share with us some of the limitations of your study that you as a board-certified pathologist know exists when conducting this study. Do you understand what I'm asking, sir?
A. Yes.
Q. Okay. What are the limitations to your study as you know them today?
A. The other way to put this around is how can I improve this study?
Q. No, sir. No, sir. I just want to know, if you were to write today, "The limitations of this study are," what would you write?
A. So this is based on the cross-sectioned data at this moment, right?
Q. Yes, sir.
A. We are not talking about what else would be included?

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Q. Yes, sir.
A. Okay. So I would say I will increase a little bit case number on this because this is from 48 women, 59 samples, and this is very important here. This is world's largest study about the precursor lesion without cancer. You cannot ever, ever fund any study with this number, and this is world largest.
But we -- as a good scientist like me, I would like to increase the case number a few more to increase the -- to expand more patients. I think that would be important for the reviewers to be highly impressed that we have even more, more than 48 women.
Q. Now, in doing so, you will be looking at more slides; is that correct?
A. Correct.
Q. Okay. And in looking at more slides is it possible that the results will change that will change your opinion regarding the association of

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chronic inflammation and the precursor lesions?
A. So -- so my opinion as in the Exhibit 2 is not totally dependent on the results. And these results can support some of the important arguments. But again, my opinion will not change, even there is a different result in my official publications. My opinion is based on my literature search about epidemiology, chronic inflammation, carcinogenesis, molecular genetics, and my 20 years of experience as a scientist and pathologist.
Q. Sir, if you were to look at another 59 slides, okay, if you were going to --
A. There should be not so many, to be honest.
Q. If you were to look at another X number of slides and every one of them shows evidence of chronic inflammation, lymphocytes, macrophages, dendritic cells, all the stuff that we

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learn in pathology and physiology, would that change your opinion regarding the association of chronic inflammation and precursor lesions of ovarian cancer?
MS. MILLER: Objection.
THE WITNESS: I cannot observe your assumption in the beginning. What you say is looking for this lymphocytes -- you are very good -- NK cells and plasma cells, that's the normal immunity.
Every single normal -- your skin, liver, brain, they have those cells.
What I'm talking about here is chronic inflammation. Chronic inflammation, of course, contain lymphocytes. But a normal tissue also contain lymphocytes; otherwise, you would get sick, you would get infected, and sepsis.
So what I mean chronic inflammation is, as compared to

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normal tissue, like I say increase the number and density of those cells.
BY DR. RESTAINO:
Q. So if you --
A. That's very important.
Q. If you were to look at X number of slides --
A. Right.
Q. -- and those X number of slides all showed evidence of chronic inflammation associated with the precursor lesions, would your opinion in this regard change?
A. I think it's a purely hypothetical. But I can tell you one thing. Based on all scientific practice, when you see zero of 10, then you don't know what's the other two, right. And then if you look at zero -- okay. How about we start over again.
We look at two cases and they have no chronic inflammation. So we are not really sure whether this is -- we

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are really confident about that.
But when you look at this number and the -- are you listening?
Q. I am listening. I'm reading too.
A. So if there is zero of this 48 cases, the probability, you know, probability, right, the chances would be extremely, extremely low.
So of course I cannot predict what happens. But I think the likelihood that we'll see chronic inflammation in those STIC, p53 signature, without cancer, would be very, very low.
And especially I would not include another 100, 200 cases, because there's a limitation of the science. There's no such material.
Probably I will increase a few number of cases.
Even this, in a single one, and this -- use a P-value, 95 percent confidence interval, you know that,

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right? So I think we are pretty safe to reach the conclusion, because we have a really solid basis, zero, of any cases we found.
Q. Did you obtain consent from the women from whom these slides came from to evaluate the slides?
A. I think I answered that question again, already.
We just follow the IRB. What IRB allows to do, we just do it. So I cannot reveal any details, that is privileged and confidential.
Q. Would one of the limitations of your study be that you did not have the associated medical records of the women?
A. What does that matter? As a scientist, again, the purpose is for the official paper. Again, I don't know what is the title of the official paper is, but the report, as in the Exhibit 4, this table, it is very clearly we try to answer one single question. But in the

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paper we may need to answer many questions.
But for this specific one, we just want to answer whether -- this is very important -- whether the ovarian cancer precursors, like p53 signature and STIC, has any chronic inflammation. If no, ovarian cancer is not related to chronic inflammation.
It could be related to other etiologies, that we, scientist, we are fighting for to look for and to help the women with ovarian cancer.
Q. And is it your opinion that the medical history of the women from whom these slides came from is irrelevant for your diagnosis?
A. No, definitely not.
Q. Then my question --
A. I said -- okay.
MS. MILLER: Can you let him finish?
THE WITNESS: I have not finished yet.

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What I have said is for this particular study -- you can look at here -- I want to know whether there is increased inflammation associated with those precursor lesions.

So in this study, I don't need clinical information. But in other -- many other ways, other studies, we need that information. Okay. So it depends on the specific question you want to ask. You cannot say it's in general not. It's not fair.

BY DR. RESTAINO:

Q. Are there other limitations, other than increasing the case number. As you sit here today, can you share with us any other limitation of your study?

A. Limitation to this particular question?

Q. Yes.

A. Or study I want to publish? I'm confused.

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Q. The study report that you have in front of us.

A. Study report. Very good.

Q. Are there other limitations --

A. Very good.

Q. -- other than the case number and you did not have access to the medical records, are there any other limitations?

A. It doesn't mean that I cannot access the medical records.

Q. Did you?

A. I don't think it's relevant to this study.

Q. Okay. If you would turn now to -- yes, thank you.

A. Which page.

Q. Other than increasing the case number and the -- at this time, not review of the medical records, are there any other limitations to your study that you can share with us?

MS. MILLER: Objection.

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THE WITNESS: I already answer your question.

For this particular questions, I think that's the limitation I can think about.

But for the in the future study, because it has not come yet, so I don't know what's their limitations.

BY DR. RESTAINO:

Q. So is it fair to say we cannot rely upon this interim study for a description of the limitations and how those limitations may affect our reading of your conclusion?

A. Already -- okay.

MS. MILLER: Objection. Please, Doctor. Ten seconds.

THE WITNESS: I have no patience.

MS. MILLER: I know. I'm aware. That's very honest of you. But please give me a chance. I know you're excited to answer the

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question.

THE WITNESS: I'm very excited. Very.

MS. MILLER: I can see.

BY DR. RESTAINO:

Q. Is it fair to say, Doctor, that we cannot rely upon this interim study for a description of the limitations of your study?

MS. MILLER: Objection.

THE WITNESS: Yeah, could you repeat one more time, slowly and using simple language about it?

BY DR. RESTAINO:

Q. You're -- you're very comfortable using English, are you not?

A. It depends.

Q. As a matter of fact, you quote Shakespeare at times, don't you?

A. What do you mean that?

MS. MILLER: Objection.

BY DR. RESTAINO:

Q. Do -- you don't know what I

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mean by quoting Shakespeare. You know who Shakespeare is?
A. I don't think this is my opinion in my report.
Q. No, it probably isn't. But have you quoted Shakespeare at lectures?
A. I don't know it's me or my co-authors, I cannot remember.
Q. I'm asking you. Have you --
MS. MILLER: He said he doesn't remember.
BY DR. RESTAINO:
Q. -- ever been videotaped wherein you've quoted Shakespeare?
A. For what purpose?
Q. For educating lay people, perhaps? Have you ever heard of the Endometriosis Foundation?
A. Yes.
Q. Have you ever -- have you recently been interviewed by them?
A. I need to double-check. I never see the interview.
Could you show me?

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Q. It's your interview, sir. And you can just look for it on YouTube and -- and on the internet. But you -- you speak English quite well in the interview wherein you quote Shakespeare, is that true?
MS. MILLER: Objection. Let's just take down the temperature of it. He is not purporting to not understand things he understands and that's what you're insinuating.
DR. RESTAINO: I'm not insinuating anything. I'm saying it.
BY DR. RESTAINO:
Q. Now, Doctor, let's turn to Page 24 of your study report. The study report.
And you see you have a question to ask in the middle, sir?
A. Yes.
Q. And in the middle of that paragraph, you have language,

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"accumulating evidence suggests."
Do you see that, sir? It's right about the middle -- as a matter of fact it's right above all the references. There's a sentence that starts "accumulating evidence"?
A. Okay. I saw it.
Q. And I'll read it and just make sure I read it correctly, sir. "Accumulating evidence suggests that serous tubal intraepithelial" -- "epithelial carcinoma (STIC) or its precursor lesions, including p53 signature and serous tubal intraepithelial lesions (STIL) located at fallopian tubes or cortical inclusion cysts of the ovary, are the precursors of ovarian HGSC." And then there's a bunch of references.
Did I read that correctly, sir?
A. Yes.
Q. And that is your opinion today, that these precursor lesions are

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the precursors of ovarian high grade serous carcinomas; is that correct?
A. So are you -- are you asking me about my opinion where is the precursor lesions located?
Q. No, sir. I'm just asking, is it your opinion today as you put in your expert report, that the -- that these precursor lesions are the precursors of HGSC?
A. That is my opinion, yes.
Q. And HGSC, so there's no confusion, is high grade serous carcinoma?
A. Perfect.
Q. Okay. Thank you.
Now, I'd like to hand to you what we have marked as Shih Exhibit 29.
(Document marked for identification as Exhibit Shih-29.)
BY DR. RESTAINO:
Q. And it's an article by Trabert, et al. Have you seen this

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article before, sir?
A. May I have the time to see the content in order to recall my memory, okay. Just a few -- give me a few seconds.
I don't recall this paper.
Q. You don't. Do you recall writing an editorial about this paper?
A. Well, maybe. I need to see -- make sure that I -- this bringing to my memory first.
Q. As you sit here today, do you recall writing and publishing that this was an important study for which the authors should be congratulated? Does that sound familiar?
A. I cannot recall the sentence. You have it -- can you show me, please?
Q. I just want to know if you recall saying that. The literature will show what the literature shows.
If you would turn to Page 755 of this paper. And are you

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there, sir?
A. Let me see.
Okay. In Table 3 you meant?
Q. No. Just on Page 755, if you look in the right column, all the way down, that little paragraph that starts and goes over to the next page.
Do you see that, sir?
A. Starting for "STIC is found"?
Q. Perfect.
A. Okay.
Q. "STIC is found with late-stage high-grade serous carcinomas in 11 percent to 61 percent of cases when the tube is extensively scrutinized; however, limited molecular data suggest that STIC is not always the source of carcinomatosis. Reference Number 13."
Did I read that correctly?
A. 13, let me see which reference. Is Chan, by Chan, et al. STIC associated with high grade serous carcinoma, systemic review. 2017. Okay.

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Q. Did I read that correctly, sir?
A. Yes. This is the word in the paper. But it may not --
Q. Okay. Can you tell us what is meant by the word carcinomatosis?
A. This is a term that medical doctors and scientists used to the spread -- the spread of ovarian cancer, in peritoneal cavity or elsewhere.
Q. Does carcinomatosis only apply to ovarian cancer?
A. No.
Q. Now, what they write here is that the STIC lesions can be found as little as in 11 percent of cases when the tube is extensively scrutinized; is that correct?
A. But this is referred to Reference 13. It's not --
That's for me?
MS. MILLER: Yes.
THE WITNESS: Okay. Thank you. I'm sorry.

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BY DR. RESTAINO:
Q. Do you agree that that's what the statement says, that STIC is found with late-stage high-grade serous carcinomas in 11 to 61 percent of cases?
That was what is written in a study that I represent to you, you describe as an important study for which the authors should be congratulated?
A. No. This is for the Reference 13, okay? So it's not this paper. It's a Reference 13. So you need to go back to original paper by Chan, et al.
Do you have the paper so we can discuss it further?
Q. Is it your knowledge as you sit here today, that STIC is found with late stage high grade serous carcinomas in 11 to 61 percent of cases when the tube is extensively scrutinized?
MS. MILLER: Objection.
THE WITNESS: So could you repeat your question and what do

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you -- what is your specific question that you want me to answer?
BY DR. RESTAINO:
Q. Is it your --
A. And your question about Number 13, then we need to review the article. We can discuss. I'm happy to do that.
Q. I want to discuss what was published by Trabert, et al., last year, in a study you described as an important study for which the authors should be congratulated.
Is it your expert opinion that STIC lesions are found with late stage high grade serous carcinomas between 11 and 61 percent of the time?
MS. MILLER: Objection. Multiple objections to this question. You are refusing to show him where he made this statement. It's completely taken out of context. We don't -- I

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think you should show him his editorial to be fair.
THE WITNESS: Number 13.
MS. MILLER: And he's saying that he cannot respond to this question without seeing the underlying study that it cites. And you are asking him if he agrees with it, and he's saying he wants to see the study to know if he agrees with it.
THE WITNESS: Yes.
MS. MILLER: I think those are reasonable points that he's making.
BY DR. RESTAINO:
Q. Okay. Let's move on then to the top of Page 756.
Very first sentence on the next page, sir. Top of Page 756. They write, Trabert, et al., writes, "A recent genomic analysis revealed STIC as a precursor of sporadic high grade serous carcinoma in 50 percent (4 in 8) of

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tumors, but also suggested that 25 percent (2 in 8) of STICs were metastases from other organ sites, (e.g., endometrium)." And Reference 31.
"If corroborated these data challenge the view that identification of STIC automatically justifies labeling a concurrent cancer as a tubal primary."
Did I read that correctly?
A. This has been written in the paper, in the discussion. It's not the author's results. So don't get confused about their discussion and their data. Okay.
So this is in a discussion.
And also you see the 31, the Reference 31. So it's by Eckert, published in 2016, Cancer Discovery.
So could you please show me the Cancer Discovery paper, and I can show you what's going on.
Q. Doctor, as you sit here today, do you recall any paper describing genomic analysis revealing STICs as

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precursors of sporadic high grade serous carcinoma in 50 percent of tumors and also suggested 25 percent were mets from other organ sites.
Do you recall that?
MS. MILLER: Objection.
THE WITNESS: You need to show me the documents before further discussion.
BY DR. RESTAINO:
Q. While we're looking for that and pulling it to show you, can you explain to the court, what are metastases? What is meant by the word "metastases" as it relates to cancer?
A. Sure. That's my pleasure. So metastasis is a term that is broadly used by cancer biologist, cancer geneticist, and also pathologist. For me, and many people will agree, that metastasis is an additive -- is an additive process that the tumor cells in their primary location need to break their basement membrane and go into the

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stroma, S-T-R-O-M-A, stroma tissue, and to find the lymphatic or blood vessel and go into there and circulate.
Then -- and it's only 50 percent, then circulate, because you are asking me about metastasis.
Q. I just asked you the definition of metastasis. Would you agree that a metastasis is the spread of cancer from a primary tumor to a distant site?
MS. MILLER: Objection.
BY DR. RESTAINO:
Q. Simple as that. Would you agree that's what is meant by metastasis in cancer research?
MS. MILLER: Objection.
THE WITNESS: It depends on who you are asking. For me, okay, you want to ask me my opinion --
BY DR. RESTAINO:
Q. Do you disagree with that definition?
A. No, I did not say that.

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Okay, as I said, my opinion, metastasis is an additive process that need to leave the primary site, go into broad circulation and settle down in the other place.
Q. So if there are metastatic lesions in the fallopian tube, then by definition, those metastatic cells have come from somewhere else, correct?
MS. MILLER: Objection.
THE WITNESS: I would say disseminated, not metastasis. So this is quite confusing, even in pathology field.
BY DR. RESTAINO:
Q. Well, if we go to the Trabert study.
A. Trabert. Okay.
Q. Okay. And 756, these researchers state that -- they use the word "metastases." They do not use the word "disseminated." Would you agree?
A. It was written that way.
Q. Okay. So when you as a

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cancer biologist see the word "metastases" there, does that suggest to you that the cells they observed came from somewhere else and were not the primary lesion?
A. You can say that.
Q. Okay. Now if you can turn to what we gave to you as the Eckert paper.
(Document marked for identification as Exhibit Shih-30.)
BY DR. RESTAINO:
Q. That was their Reference 31. Do you recognize this paper, sir?
A. I remember seeing this paper. But I cannot recall in detail. So I need to --
Q. Let's read the first couple sentences of the abstract. "Accumulating evidence has supported the fallopian tube rather than the ovary as the origin for high grade serous ovarian cancer, (HGSOC). To understand the relationship

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between putative precursor lesions and metastatic tumors, we performed whole-exome" -- E-X-O-M-E -- "sequencing on specimens from eight HGSOC patient progression series consisting of serous tubal intraepithelial carcinomas (STIC), invasive fallopian tube lesions, invasive ovarian lesions, and omental metastases."
Did I read that correctly, sir?
A. It was written this way.
Q. Okay. Thank you. And putative precursor lesions means reported, or reputed to be precursor lesions, correct?
A. I get lost. Let me see. Which line are you at right now? I'm sorry. Which line?
Q. One, two, three lines down.
A. Three down. Okay.
Q. Underneath accumulating evidence, they describe them as putative precursor lesions.
Do you see that?

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A. "Phylogentic analyses supported STIC as a precursor." That's what you are talking about, or before that?
Q. Just the third line, sir.
A. From the top?
MS. MILLER: "To understand the relationship"?
DR. RESTAINO: Right next -- pardon me?
MS. MILLER: Are you at "To understand the relationship"?
BY DR. RESTAINO:
Q. Forgive me. Yes. "To understand the relationship between putative precursor lesions," do you see where I am?
A. Okay.
Q. Okay. Now, stop at the word "putative."
Do you see that?
A. That's the author's opinion.
Q. In this peer-reviewed published paper, correct?

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A. This is not peer-reviewed. I'm sorry. This is a true original publication. I think you get confused.
Q. You don't believe that this paper by Eckert, et al., that has been published in Cancer Discovery is peer-reviewed?
A. It's -- it's peer-reviewed, but it's not review paper. Maybe we got lost from --
Q. Well, we know it's not a review paper. But it's been reviewed by peers of these authors. Would you agree?
A. That's correct.
Q. Okay. And they allowed the use "putative precursor lesion," correct, because that's why it's in the article?
A. In science we just use a more liberal way to describe things, because we are not very sure about things.
Q. Well, you're sure that these lesions are precursors to high grade serous carcinoma, as you write in your

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expert report. You don't state they are putative. You say they are precursor lesions, correct?
A. This is based on -- there are many hypotheses --
MS. MILLER: He's in the middle of answering a question.
DR. RESTAINO: I know. I'm just asking if you are ready for a break.
THE WITNESS: So I --
DR. RESTAINO: I'm sorry. I misunderstood what you were asking, or what you were -- my -- my -- I misread your body language. And I was -- I thought I was answering you. I'm sorry.
MS. MILLER: No, no, no. Wait.
BY DR. RESTAINO:
Q. Forgive me, sir.
A. Could you repeat one more time your question?
Q. Yes. These authors describe

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the lesions as putative precursor lesions. You state in your expert report that they are precursor lesions. Do you disagree with these authors?
A. In order to answer your question, I need to give you background about the -- this field. Because this is a medicine field --
Q. I don't need background on it, trust me on this, sir, I don't need background on it. I just need to know whether it's your opinion that the STIC lesions and the p53 signature lesions are putative precursor lesions, or if they are precursor lesions.
A. I would say they are most biologically plausible precursors at this moment.
Q. Okay. At this moment. But it might change, because research never finishes, correct?
A. But we are talking about the science here as you elaborate in the very beginning.

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Q. Okay. Now, if you go down to Page 1348 of the Eckert study. Are you there, sir?
A. Yes.
Q. And it's the first full paragraph in the right column.
A. First.
Q. Okay. The first full paragraph starts with "the data presented herein."
Do you see that, sir?
A. Yes.
Q. "The data presented herein may lead us to develop our perception of STIC further: STIC in HGSOC could be primary or metastatic."
Do you agree with that, sir?
A. No.
Q. You disagree with these authors that it could be a primary, or it could be metastatic?
A. I disagree about the statement.
Q. Okay. Sir, did you, in your

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study for which we have your interim report, did you conduct phylogenetic analyses of the material?
A. Could you repeat that question one more time?
Q. In the slides, the materials you reviewed for the study report we're discussing, did you conduct phylogenetic analysis?
A. The study that's in Exhibit 4, as I said many times, the purpose is to determine whether there is a chronic inflammation associated with those precursor lesions. So what is phylogenetic coming to this picture? I cannot understand your question. It's not relevant.
Q. Okay. Sir, if you would go back to the abstract of the Eckert paper that we're looking at.
A. Okay.
Q. Okay. And now to make it a little easier, it's one, two, three, four, five lines up from the bottom of

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the first paragraph of the expert. There's a sentence that starts with "phylogenic analyses."
Do you see that, sir?
A. No.
Q. It's about four or five lines up from the bottom of the first paragraph.
A. Ah, the first paragraph. Okay. One, two, three, four, five. Phylogenetic analysis...
Q. Do you want to read that into the record out loud, sir, or you want me to?
A. You do it. You do a better job.
Q. Phylogenic -- I don't know. Phylogenic --
MS. MILLER: Slowly.
THE WITNESS: I'm not English speaking.
BY DR. RESTAINO:
Q. You know, English is my second language and I don't have a first.

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"Phylogenic analyses supported STIC as precursor lesions in half of our patient cohort, but also identified STIC as metastases in two patients."
Did I read that correctly, sir?
A. That has been written this way.
Q. Okay. So now my question is, did you conduct a phylogenic analysis of the tissue that you examined for your study report?
A. Again, my study report is not answer this question whether the STIC is a precursor or not. I think it has been shown in many papers.
The question is, what I want to show is, whether there is chronic inflammation associated with the precursor. I think that is most important question. Whether chronic inflammation has ever, ever played a role in this tumor initiation.

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I hope you agree that this is the best study to show in this way, rather than a genetic tree, because it is not relevant. We are answering different questions.

Q. Okay. But in order to answer the question that you seek to -- to answer, as Trabert stated in referencing --

A. Trabert?

Q. The Trabert study.

A. Yeah.

Q. They referenced, remember, Number 31, on Page 756, in the right column. And they referenced the Eckert study showing that 25 percent of the tumors that are --

A. Tumors, are you talking STIC or carcinoma?

Q. -- that 25 percent of the STICs were metastasis from other organ sites, correct?

A. That has been written.

Q. Okay. Now, it is your

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hypothesis, that chronic inflammation was not seen in the STIC lesions and the p53 signature lesion slides that you observed, correct?

MS. MILLER: Objection.

THE WITNESS: I think I already tell you about the answer.

BY DR. RESTAINO:

Q. Of the slides that you saw?

A. Which slides are you talking about?

Q. The 59 slides that make up your expert report, sir.

MS. MILLER: Objection. They do not make up his expert report.

DR. RESTAINO: Of the study report.

BY DR. RESTAINO:

Q. The 59 slides that are listed in your study report.

DR. RESTAINO: Thank you, Jessica.

MS. MILLER: Sorry. I just

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want clarity.

BY DR. RESTAINO:

Q. Of those 59 slides as you sit here today, how many -- what percentage of the STIC lesions developed there at the primary site that you examined or were metastases from elsewhere?

MS. MILLER: Objection.

THE WITNESS: You ask very important question. I think the methodology matters a lot in this field.

So many study in the past, they analyze, can I show you the Figure 2? I think it will be much easier to explain it to you. Or you don't need it? I think it will be useful for you.

BY DR. RESTAINO:

Q. Oh the diagram. The cartoon?

A. The cartoon, yeah. Right.

Q. Sir it's a simple question.

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What percentage of the STICs lesions that you evaluated were metastases?

A. Do you remember, when you read my study report carefully, I say -- this is very important. I think this is a whole confusing point for your part.

I say in order to prevent this metastases, I intentionally focus on studying those STIC and precursor signature with cancer, so they cannot metastases.

Q. Were there STIC lesions in women who had concurrent ovarian cancer?

A. I include those as well.

Q. And what percentage of those STIC lesions were metastases?

A. There are very few. So it's not the purpose of this study report. The study report, again, is not for that purpose.

Q. Would -- would you agree that if sub -- that if X number of the STIC lesions you evaluated were

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metastases, then the absence of chronic inflammation around that STIC lesion, as you're looking at it, might not exist because the chronic inflammation is back at the primary tumor, wouldn't you agree?
A. I think this is too long question. Could you break up small one, and simple one individually so I can better answer you and more effectively.
Q. If chronic inflammation caused cancer somewhere, and that --
A. If. Okay. In ovarian cancer or in other tissue types?
Q. In an anatomic site where metastases could go to the fallopian tube. And that tumor spread or metastasized to the fallopian tube and was on some of the slides that you looked at that were labeled STIC, you wouldn't expect to see chronic inflammation around those lesions as the precursor to their development, would you?
MS. MILLER: Objection.
THE WITNESS: I think you're

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asking whether the STIC with and without cancer, they are associated with chronic inflammation; is that correct?
BY DR. RESTAINO:
Q. I was asking about the STICs that were present in the slides from women who had a concurrent ovarian cancer.
A. Yes.
Q. Were those STIC cells primary there at the site that you examined, or were they metastases or don't you know?
A. That, I don't know.
DR. RESTAINO: The water is having its effect on me. May we take a break?
THE WITNESS: I think that's a good idea.
THE VIDEOGRAPHER: The time is 11:43 --
MS. MILLER: It's 11:43. I was going to try to go till lunch.

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But I guess you only -- do you want to come back and do a half an hour and then go to lunch? It's kind of early.
DR. RESTAINO: Does that work for everyone?
MS. MILLER: Yes.
DR. RESTAINO: I just need to --
THE VIDEOGRAPHER: The time is 11:44 a.m. We're going off the record.
(Short break.)
THE VIDEOGRAPHER: The time is 12:03 p.m. We are back on the record.
BY DR. RESTAINO:
Q. Welcome back, Dr. Shih.
A. Can I have one small comment here? Or no? There's some confusion about the terminology we just discussed about the STIC.
Q. Sir, I don't have a question pending. What I should have shared with

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you in the beginning of the deposition, and I forgot to do so. There are times when I might ask you a question that I'm asking, just yes or no, but you want to explain it further.
At the end of the deposition today, Jessica gets to then also ask you questions.
"Now, do you remember when John asked you this question? Would you like to expand upon it?"
So if you're cut off, you're not totally cut off. You'll get a chance to explain it.
I would like for you to go to your expert report. And if you look on Page 10 of the expert report, you have a table there, correct?
A. Right.
Q. And then under the table that's a paragraph that's listed, or has a designation of Number 1, correct?
MS. MILLER: "The new paradigm"?

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BY DR. RESTAINO:
Q. Yes. The new paradigm.
A. The new paradigm.
Q. Yes. "The new paradigm of ovarian cancer genesis -- that ovarian serous carcinomas originate not in ovarian tissues, but rather in the precursor lesions in the fallopian tubes -- has been widely accepted (Kurman and Shih Ie, 2011, 2016; Kurman and Shih, 2010; Wu, et al., 2018)."
Did I read that correctly, sir?
A. Yes.
Q. Now, the first article, Kurman and Shih Ie, 2011, that's you; is that correct?
A. Correct.
Q. And Dr. Kurman, that is Dr. Robert Kurman?
A. Correct.
Q. And did you train under Dr. Kurman?
A. I worked with him, yes.

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Q. Okay. Is Dr. Kurman an expert for Johnson & Johnson in this litigation also?
A. That's my understanding.
Q. Okay. Now, the next one is Kurman and Shih Ie, 2016, correct?
A. Correct.
Q. And that, again, Dr. Shih is you, correct?
A. Correct.
Q. The next one is Kurman and Shih 2010. And that's the same Dr. Robert Kurman and the same Dr. Shih, correct?
A. Correct.
Q. And then the final article is Wu, et al., 2018, correct?
A. Correct.
Q. And you are actually an author with Dr. Wu; is that correct?
A. I'm the co-author.
Q. You're a co-author with Dr. Wu. In fact -- yes, that's the genomic landscape paper, correct?

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A. Correct.
Q. Doctor, is it -- so for support of your opinion that the ovarian serous carcinomas originated not in ovarian tissues, but rather in the precursor lesions in the fallopian tube has been widely accepted, the only papers that you have listed to support that statement are statements -- are papers which you and Dr. Kurman are the authors, correct?
A. No.
Q. Is there another paper there that is not -- where you and Dr. Kurman are not an author?
A. So if you --
Q. Sorry, Doctor. Is there another paper listed in your expert report that does not list Dr. Kurman or you as the author?
MS. MILLER: Objection.
THE WITNESS: There are so many paper. These are review papers based on many, many

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reviews.
So if you go to references of this paper, you will be readily identifying there's many other articles.
But because we don't need to show everyone here, because, you know, based on my status and Dr. Kurman's expertise in this field, we are well recognized as the paradigm shifter along with other investigators in the nations. So I don't think this is a question here.
BY DR. RESTAINO:
Q. Okay. Sir, in your expert report that you've submitted to the court, would you agree that the only articles that you've referenced for support of your opinion that this hypothesis has been widely accepted are papers that you and Dr. Kurman are co-authors on, correct?
A. Again, they are review

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papers based on many, many original studies.
DR. RESTAINO: I'm going to move to strike.
BY DR. RESTAINO:
Q. The only papers listed in your expert report are those that you and Dr. Kurman are the co-authors on, correct?
A. They are review papers --
MS. MILLER: Objection. Please remember to give me ten seconds.
THE WITNESS: I'm sorry.
BY DR. RESTAINO:
Q. Do you agree with that statement, sir?
A. They are review papers based on many original articles.
Q. Review papers for which you and Dr. Kurman are the co-author, correct?
A. Our review paper is summary of all many original articles.

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Q. Okay. If you would go now down to your study report, which I think is Exhibit 4.
A. Yes.
Q. And go to Page 26. Actually, I think it's the bottom of 25. It's where your Table 2 is the listing of the slides.
MS. MILLER: There's nothing on the table on Page 25. I'm confused. Are you looking for this, on Page 29?
DR. RESTAINO: Yes. 29. Thank you.
BY DR. RESTAINO:
Q. 29. Who drew up this table, sir?
A. Repeat the question one more time.
Q. Who made up this table?
A. I did.
Q. Okay. Who named Lesion 1 -- who gave it a case ID of S8001?
A. This is from the slides

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labeled.
Q. Okay. So --
A. And assigned.
Q. So if you pick up Slide S8001, it already has that number on it?
A. I think it should be written on the slides.
Q. You think, sir, or you know that they are?
A. As I recall they should be there.
Q. And the next column has a diagnosis of p53 SIG. Could we agree that SIG stands for signature lesion?
A. Yes.
Q. And on that slide, S8001, does it list p53 SIG on it?
A. You mean on the slides? I --
Q. Is it listed somewhere, so that if you pick up this slide, S8001, you're able to look and say ah, p53 signature lesions?

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A. Based on this Table 2.
Q. Yes.
A. Yes. Based on this Table 2.
Q. Okay. And this slide did not have evidence of concurrent cancer, correct?
A. Yes.
Q. At the bottom of Table 2, you define, where the asterisk is, inflammation and you define it as, "Increased lymphocytic infiltrate associated with the lesions as compared to the background normal tissue of mucosa"; is that correct, sir?
A. Yes.
Q. And that's the definition you used in the entire chart for whether there was inflammation or not?
A. As I believe I also look at this plicae fusion, P-L-I-C-A-E, fusion as a sign of chronic salpingitis.
THE REPORTER: Chronic what?
THE WITNESS: Salpingitis, S-A-L-P-I-N-G-I-T-I-S.

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BY DR. RESTAINO:
Q. Okay. When -- when you make -- when you list -- listing here the diagnosis of p53 SIG, did you make that diagnosis or was it made for you already by someone in -- in listing this slide?
A. I review the slides and make the diagnosis as listed.
Q. You made the diagnosis as it -- or did you confirm the diagnosis that was listed?
A. In this study I think I made the final diagnosis. I don't care about what has been written. But I would look at the primary report and they are all consistent.
Q. So your diagnosis was consistent with the existing primary diagnoses of these slides?
A. I cannot remember I check everyone, okay. But the most important thing is the diagnosis I listed is my final decision.
Q. And I'm not trying to

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confuse you. I'm just trying to be clear.
If this is Slide S8001, and you put it under the microscope to look for the p53 signature lesions, is there a report somewhere or a listing somewhere that you say, ah, yes, p53 SIG lesions, and then you look in the microscope and you confirm it?
A. Oh, okay. I understand your question. I did not do that.
Q. You did not confirm the diagnosis?
A. No, I did not see the original diagnosis, but as you know on this page, they must have some diagnosis already. Okay.
Q. In other --
A. This says tubal lesions.
Q. Okay.
A. But I -- I just made the diagnosis by myself.
Q. How did you select or know to select the slides that had p53 SIG

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lesions in them?
A. I just search from the -- from the list we have, contending any tubal lesions or abnormalities like a cancer.
As you can see here --
Q. Yes.
A. -- it's our brain cancer listed. And that's -- that's what I did. Then I retrieve them, then I review under the microscope, and then I put a diagnosis.
Q. And then you were able to confirm the presence of the p53 SIG lesion?
MS. MILLER: Objection.
THE WITNESS: By myself.
BY DR. RESTAINO:
Q. And is that the same methodology you did with the STIC lesions, find those slides that had STIC lesions in them, look under the microscope, confirm that there was STIC lesions?

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A. This is not a confirmation study. This is a study to understand chronic inflammation. So I select those abnormal fallopian tube lesions, including cancer or no cancer. Then I make my final diagnosis.
Q. How many slides did you have to look at in order to come up with the number of slides that -- in order to come up with the 18 p53 signature lesions, how many slides did you have to go through to find those 18 slides?
A. Do you mean from the original or in our list? Because as you need to understand, so this study is all about the tubal lesions. So if there is a normal fallopian tube, usually we did not include in this study, because that's not our purpose.
So that means if we include the eligible case or cases in the list, they must have some tubal lesions.
Q. Okay. And the -- and the tubal lesions that of interest to you for

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your study that you selected were the p53 SIG lesions, or STIC, correct?
A. With -- without cancer or with cancer.
Q. Understood. Okay.
A. I should tell you, the STIC, I say here, okay, so without cancer, I think the STIC. With cancer, I label STIC, but actually it's a STIC-like lesion. Because we never know if it's a metastases of cancer or it's original ones.
Q. Okay.
A. So -- so this even for the pathologist very confusing, because STIC, what do you mean. My definition here is, under microscope, if STIC was cancer, that is STIC-like lesions. So this apply to all the deposition today. It's not only STIC, because it's too confusing.
Q. Do you use the term "STIC-like lesions" in your -- in your study report?
A. It depends. I -- I'm sorry,

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say that again.
Q. Do you use the term "STIC-like lesions" in your study report that you've performed -- that you have produced to us?
A. I don't think so. I think in that way would confuse more people. I think it's better for explanation colloquially.
Q. Would you agree that approximately 40 percent of high grade serous epithelial carcinomas don't have precursor cells?
A. Which type of cancer are you talking about?
Q. HG -- the cancer we are talking about, the high grade serous epithelial ovarian cancer.
MS. MILLER: Right there.
BY DR. RESTAINO:
Q. Would you agree that approximately 40 percent don't have precursor cells?
A. It depends on study, but I

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cannot say 40 percent exact.
Q. If you were to sit for us today and estimate for us, what would be the estimate of the number of high grade serous carcinomas do not have precursor cell lesions?
A. I think this is a question, that based on your assumption is a precursor. I want to restate your question is whether there is a STIC-like lesion associated with cancer. Then I can answer that question. Because I don't know if it is really a precursor or not.
Q. Okay. Now, you state that for example, on your Lesion 1, there's no inflammation; is that correct?
A. Correct.
Q. And the inflammation is defined as below, by increased lymphocytic infiltrate, correct?
A. Plus whether there is plicae fusion as I mentioned in my methodology in my report.

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Q. Did you observe macrophages in that slide?
MS. MILLER: Objection.
THE WITNESS: I examine inflammatory cells that can constitute our pathologic diagnosis of chronic inflammation. Whatever we are trained, I exercise here.
DR. RESTAINO: Doctor, I'll move to strike as unresponsive.
BY DR. RESTAINO:
Q. Did you observe macrophages in slides with Lesion Number 1?
A. I examine all the inflammatory cells.
Q. Does that include macrophages?
MS. MILLER: Objection.
THE WITNESS: If there is present. If it is not present, I cannot say it.
BY DR. RESTAINO:
Q. Did you examine for the

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presence of dendritic cells?
A. Which -- dendritic cells?
Q. Yes.
A. This is not in the criteria for us to diagnose chronic inflammation. Every pathologist who are practicing pathology diagnosis, they don't need to look at specific cell type to make up the inflammation.
Q. Then why did you look at lymphocytes?
A. Lymphocytes is the most important criteria to the pathologists who are able to make up, because they are most common.
Q. More common than polynuclear cells, polymorphonuclear cells PMNs?
A. PMN is a component of acute inflammation.
Q. And you observed evidence of acute inflammation in your slide analysis, didn't you?
MS. MILLER: Objection.
THE WITNESS: Yes. And I

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did not find any acute inflammation.
BY DR. RESTAINO:
Q. And --
MS. MILLER: Wait. I think you're speaking past each other.
THE WITNESS: Okay. Can we start over again?
BY DR. RESTAINO:
Q. Yeah, would you agree that chronic inflammation is acute inflammation which doesn't go away?
MS. MILLER: Objection.
THE WITNESS: Chronic inflammation is enriched by lymphocytes. They can come in from different resources. Like, autoimmune disease you don't have acute inflammation, but you have chronic inflammation. So it depends on the context and biology and the pathogenesis.
BY DR. RESTAINO:
Q. So of the components of the

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innate immune system, including lymphocytes, B-cells, T-cells, dendritic cells, macrophages, PMNs, the sole cell type that you decided to look for was lymphocytes, correct?
A. I think --
MS. MILLER: Objection. Please, Dr. Shih.
THE WITNESS: Can you repeat one more time.
BY DR. RESTAINO:
Q. So of the components of the innate immune system, including lymphocytes, beta cells, T-cells, dendritic cells, polymorphonucleocytes, PMNs, and lymphocytes, the sole type that you chose to look for in your -- in this study are the lymphocytes, correct?
A. You said in innate system including B -- T-cells. I don't think T-cells is part of innate immune system.
So I don't know what you're talking about.
Q. Okay. Then I'll strike the

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question and I'll ask you this way.
As part of the immune response the cells of the body include B-cells, T-cells, PMN, macrophages, and lymphocytes, correct?
A. You can say that.
Q. Okay. And you chose to look for lymphocytes, correct?
A. No, I said I look for inflammatory cells, including lymphocytes.
Q. Okay. Do you list in your study anywhere the presence or absence of macrophages?
A. I don't see any prominent macrophages at all in those cases.
Q. And how about PMNs?
A. I don't see any.
Q. In any of them, even in -- if you go down to Lesion Number 14, Slide ID 10146, where there's yes under inflammation, did you see macrophages?
A. I think you are talking about the STIC or STIC-like lesions. You

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are talking about every cases here? I just want to make sure that you're talking about the whole list.
Q. In this entire list, do you list anywhere -- did you quantitate the presence of macrophages?
A. I cannot recall in ovarian cancer I see any macrophages, because that -- these cells are not characteristics component.
Q. Of?
A. Of high grade serous carcinoma. Usually they are T-cell, B-cell and the plasma cells and these other things. So it could be part of it, but I did not say it here.
Q. What about the chronic inflammatory process instead of the high grade serous carcinoma? Are macrophages part of an inflammatory process?
A. No.
Q. Are PMNs part of an inflammatory process?
A. In a STIC or STIC-like

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lesions?
Q. In anything?
A. Well --
Q. Any inflammation that goes on in the body.
A. Ah, okay.
Q. Tendinitis from playing too much tennis.
MS. MILLER: Wait a minute. Can we have just one question? Because now we're having a back and forth. I just want to know what the question is so I know it's objectionable or not, and then I want him to answer.
BY DR. RESTAINO:
Q. In the body's response to inflammation, do the cells include PMN, macrophages, lymphocytes, dendritic cells? Agreed?
A. It depends on what type of inflammation and the insult and tissue type.
Q. Okay. Let's talk about

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chronic inflammation.
A. Okay.
Q. What are the normal immune cells that you as a pathologist would look for when making the diagnosis of chronic inflammation?
A. We look at any inflammatory cells. Again, okay, so the lymphocyte, macrophages and those that we can easily identify by H&E slides under microscope, we do that. So it's not based on only lymphocytes. It's based on macrophages and other inflammatory cells taken together.
Q. Okay. Thank you. We'll move on.
Under the case ID column, just to clear up some questions, the first seven slides are S80001 to S80007.
Do you see that, sir?
A. Yes.
Q. But then the next one is 10150?
A. Yeah.

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Q. Why?
A. Just a different labeling system. There's no -- nothing curious.
Q. Is that your labeling system or the way the slides were labeled in the tissue -- in the slide bank?
A. I cannot remember that. My job is to pull out the slides and make my diagnosis and record my results.
Q. Couple more down. When I'm looking at Lesion 9 and 10, there are two slides that have Case ID 10149.
Do you see that, sir?
A. 10 --
Q. 10149. It's Lesion Number 9, Lesion Number 10?
A. 9, 10, yes.
Q. And why are there two IDs -- same identical IDs assigned to two slides?
A. So I think there's a Figure 2, would be important for you. You need to understand that ovarian cancer lesion here, has multiple lesions

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before the cancer develop. That's really our really nice study to show to the scientists that the fimbriated end of fallopian tube contain multiple precursor lesions, and our hypothesis is only one, or very few, maybe only one, can develop into carcinoma.

So that's why this carcinoma can destroy the other -- other tissue in the fallopian tube.

And usually what happens --

DR. RESTAINO: Sir, I'm going to move to strike.

BY DR. RESTAINO:

Q. I'm just asking you, why are these two slides -- why do they both have the same ID number?

A. They have Signature 1 and Signature 2. Can you see that?

Q. I see that.

A. Yeah. So there's one here, two here. These are discrete lesions for the same patient. Is that clear?

Q. Okay, sir.

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A. Okay.

Q. So 10149, that would refer to the same patient?

A. Correct.

Q. Okay. Thank you.

And then going down -- and I'm not going to go through all these different questions because I think I understand now.

These numbers, the case ID number, you didn't assign that case number to a particular slide. That was the existing case number for that slide; is that correct?

MS. MILLER: Objection. I thought he said he didn't know.

THE WITNESS: I think I answered your question.

BY DR. RESTAINO:

Q. For the very first slide, Lesion 1, S8001, did you make up that case ID number?

MS. MILLER: Objection.

THE WITNESS: I told you

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already.

MS. MILLER: Objection. Asked and answered.

Please, Dr. Shih, give me five seconds. I'll give up on ten seconds. I'm asking now for five.

THE WITNESS: Okay.

BY DR. RESTAINO:

Q. I'm sorry, I keep asking the question. I still don't understand who came up with that case ID number, you or was it an existing ID number?

A. I cannot recall.

Q. Okay. And would it be the same thing, like for example, if you go down to the last four instead of the numbers that we've been seeing above, now all of the sudden we have 20001 NFT.

Do you see that, sir?

A. Yes.

Q. Who came up with that number, you or somebody else?

A. These four cases, NFT, do you know what is NFT? Normal fallopian

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tube.

Q. Okay.

A. So, as in my report, if you read it, it says that in order to come out with control and we combine the previous study in Ardighieri study and the new cases of fallopian tube, so that's -- we randomly select from our file of the normal fallopian tube to be included.

Q. Okay. So therefore, with those four, when you sat down at the microscope and you took the histology slide 2001 NFT, you knew that the previous -- or the preexisting diagnosis was normal fallopian tube, correct?

A. In our diagnosis, we say histologically unremarkable.

Q. Yes, but who made the initial diagnosis of normal fallopian tube leading to the case ID 20001 NFT?

A. I don't know. It's for our files.

Q. Okay. In conducting a

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research study such as this one or any other that you have done in the past and published, there are studies where you describe yourself as being blinded to preexisting information and looking at a slide for the first time, correct? Do you understand what I mean by blinded?
A. In some studies.
Q. Yes. And what's the reason for blinding in some studies?
A. The blinded study are important for the correlation with clinical outcome. Like survival, resistant to chemotherapy, et cetera. And we usually, what happens is for this blinded, so we have clinical data about clinical outcome, and a pathology review the slides without knowing the clinical outcome. So I think these are blinded studies.
Q. Okay.
A. Because when you look at pathology slides, you are not a diagnosis, it cannot be blinded. So it

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is different form of research designs.
Q. When a -- when a pathologist is blinded for specific studies, that's to reduce bias, correct?
MS. MILLER: Objection.
THE WITNESS: Can you say that again?
BY DR. RESTAINO:
Q. The use of blinding is to reduce the potential for bias --
MS. MILLER: Object again --
BY DR. RESTAINO:
Q. -- agreed?
MS. MILLER: I'm sorry. Objection.
THE WITNESS: What kind of bias you -- you are talking about?
BY DR. RESTAINO:
Q. How about, are you familiar with the term "confirmation bias"?
A. Maybe.
Q. You don't know?
A. I know. But I don't know what that mean to you, but I have my own

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definition.
Q. What is your definition, sir?
A. Meaning if you know something like a clinical outcome that will affect your interpretation of the result. But for the pathology diagnosis it's black and white. You cannot -- you don't have discount bias.
Because if we have a bias in pathology practice, then what happened to the patient's diagnosis, right?
Okay. So for example, we have a tissue, perform a biopsy on a woman with a lump in the breast. We want to know, woman here want to know if this is benign or malignant. We can answer, oh, this is malignant. So we -- we change our diagnosis or set our mind to this opinion. No.
This is really breach the -- the pathology practice. So a pathologist is evidence based. It's different information like data and -- and risk

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factors and this and that because they can really bias.
Pathology, it's really black and white. Otherwise what pathology diagnosis need to exist in medical system? So pathology is a finite diagnosis. You cannot change -- you cannot challenge that.
Q. And bias is a form of confounding, correct?
A. It depends what you mean. Could you be more specific for that?
Q. Do you understand -- understand the word confounding as it's used in science?
A. So my confounding definition is some factors, they are not driving, but they are associated with the outcome. For example, in many epidemiology studies, especially those with very low risk, 1.3, they are full of confounding factors.
Q. Right. Would that hold true for passive smoking and lung cancer,

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which has an odds ratio of 1.3?
A. Can you say that one more time?
Q. Would that hold true also for passive smoking and lung cancer which has an odds ratio of 1.3?
A. I am not the expert in that field. So I cannot answer your question. I am here to answer the causal relationship of talc, including Johnson & Johnson powder, whether it cause ovarian cancer, any biological plausibility.
Q. What steps did you take in conducting your study to rule out confounders?
A. Which -- which study?
Q. The study we are talking about, the study that you have produced to us, what steps have you taken to rule out confounding elements?
MS. MILLER: Objection.
THE WITNESS: So your question is, what are the

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confounding factors in this study?
BY DR. RESTAINO:
Q. No, sir. What steps did you take to rule out confounding factors?
A. Okay. I don't have any pre-set mind whether ovarian cancer precursors, including p53 signature and STIC without cancer is inflammatory or not, because if yes or no, they are big deal in this field. They are equally exciting in the biological studies. So I welcome any good results that can show convincingly yes or no. If yes, we can do a whole set of new studies, quite exciting. And the -- the opposite is true, if there is no inflammation, we just direct to the other research field to answer what is the course, the biological basis of ovarian high grade serous carcinoma.
DR. RESTAINO: I'll move to strike as nonresponsive.
BY DR. RESTAINO:
Q. Doctor, can you define for

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us what -- what the word lymphocytopenia means?
A. Could you spell it for me?
Q. As a physician and pathologist, you don't recognize the word lymphocytopenia?
A. Lymphocytopenia.
Q. Lymphocytopenia.
A. That means -- okay. If I understand your pronunciation correctly. Means -- penia means deficient or lower. The less means. Lymphocyte has reduced their number in circulation.
Q. Only in circulation?
A. That's what I understand. Usually people use that term in cancer patient after chemotherapy.
Q. If a patient has documented lymphocytopenia as determined from a -- from blood test, and decreased lymphocytes circulating in the blood and serum, would you also expect to see less lymphocytes at sites of inflammation?
A. So again, I tell you

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already -- I have told you already, that two claims whether there is chronic inflammation as shown in this Table 2, it's based on not on the absolute number of lymphocytes I see as compared to the adjacent normal or histologically unremarkable mucosa as compared. If there is a cyto -- lymphocytopenia, okay, so you should be able to see increased number as compared to the normal mucosa for the same leukopenia patient.
Q. Unless there were confounding factors present, correct?
A. Say that again.
Q. Unless there were confounding factors present, like, for example lymphocytopenia. And if one had lymphocytopenia that was drug-induced from example for the anti -- chemotherapeutic Imuran, I-M-U-R-A-N, azathioprine, then if that patient has drug-induced lymphocytopenia, regardless of what tissue you look at, there's going

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to be a decreased number of lymphocytes present, isn't there?
A. Yeah, but that will not affect my chronic inflammation diagnosis. I use the comparison to the same area.
Okay. So if in the normal, it's 100, and we have 300 in the STIC, that's chronic inflammation. In the leukocytopenia, if you only can count 50, okay. It's lower, right? Leukocytopenia, right, 50. Now if you count 100, now you still call it chronic inflammation.
So it's relative, rather than -- so I don't think this is a confounding factor at all.
Q. How many of the women from whom these slides were obtained were on azathioprine?
A. What is that? Can you spell it for me.
Q. A-Z-A-T-H-I-O-P-R-I-N-E. The generic name that -- the brand name is Imuran, I-M-U-R-A-N, or Azasan

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A-Z-A-S-A-N. They are cancer therapeutic agents.
A. I'm a pathologist. I am not a medical oncologist.
Q. Do you know if those drugs can cause lymphocytopenia?
A. I am a pathologist. I am not a medical oncologist to have this knowledge.
Q. How many of the women from whom these slides were obtained were on carbamazepine, also known as Tegretol, used to treat seizures, nerve pain, bipolar disorders. How many patients suffered from those conditions and was on carbamazepine, also known as Tegretol?
A. I don't think this information is relevant to my study and my conclusion at this moment.
Q. Is -- do you know if carbamazepine causes lymphocytopenia?
A. Again, I'm not medical oncologist. I did not directly take care of the patients. I -- my job is to

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review the -- under the microscope to see whether there is increased inflammation as compared to the adjacent normal tissue from the same patient, no matter what he actually take.
Q. How many patients took cimetidine over-the-counter, also known as Tagamet?
A. Could you spell the.
Q. Cimetidine is C-I-M-E-T-I-D-I-N-E. Tagamet. Do you know how many of them took Tagamet over-the-counter?
A. This is not relevant to our discussion.
Q. Do you know if Tagamet is associated with lymphocytopenia?
A. As we discussed, cytopenia is not a confounding factor in my study.
Q. Are you familiar with the class of drugs known as the corticosteroids?
A. I know the name, but could you specify which corticosteroids we're

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talking about. There are so many different kinds for different --
Q. The class itself is known as anti -- or is known as antiinflammatory drugs, correct?
A. Again, I'm not the first-line medical doctor. I'm a pathologist. So -- and most importantly, I think your questions are not relevant to my study.
Q. If a patient had rheumatic fever -- excuse me -- has rheumatoid arthritis and was taking prednisone for that condition, prednisone, a corticosteroid, is an antiinflammatory agent, correct?
A. Again, this is also not in my opinion and my expertise.
Q. Okay. Are you familiar with methotrexate?
A. I think my answer is the same. This is not relevant. It's not confounding factors, because I diagnose chronic inflammation in my -- in my

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specimens based on comparison, based on comparison of the -- whether there is chronic inflammation associated with p53 signature, STIC, and the adjacent normal tissue at the same time, as I give you the example. Normal patient is 100 -- so 100, you get 300, then you have chronic inflammation.

Now if the patient take methotrexate, steroid, whatever that cause leukopenia, it will reduced from 100 to 60. Okay. Then if I see is 80 or 100 in the STIC, and then I will call it chronic inflammation.

So this is definitely not confounding factors because of my study design.

Q. Sir, if you look at your Table 2, and we'll just look at Lesion Number 7.

DR. RESTAINO: I'm going to move to strike your previous answer as unresponsive.

BY DR. RESTAINO:

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Q. Let's look at Lesion Number 7. It's a STIC lesion, no concurrent cancer, no inflammation, correct?

A. Number 7 you mean? The number is S --

Q. Yes, it's S80007. Okay. That was a histology slide that had evidence of a STIC lesion in it, correct?

A. I saw it.

Q. Okay. What slide did you compare that against?

A. The same slide, because remember, this is a Figure 2. The STIC is only a microscopic focus. It is very small. You cannot see it in the gross. So it only occupies less than one percent of the tissue I examined. So there's a 99 percent -- at least 99 percent more histologically unremarkable.

Q. Okay. So you're comparing the STIC lesion in that slide compared to the normal tissue in that same slide? Is that my understanding?

A. That is one way.

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Q. Is that the way you did it?

A. That's only one way.

Q. What else did you do?

A. The other way is to compare to the NFT, as you just mentioned in the inquiry. And so we have two references.

Q. For the same patient?

A. Different patients.

Q. So --

A. We compare same patients and also compare two different patients.

Q. So you're comparing the presence and quantifying the inflammatory process in Patient A to Patient B who has normal fallopian tube, and making a comparison; is that true?

A. I think you have a wrong statement. I did not quantify. Again, I used the pathology knowledge and background and training, experience, to make the chronic inflammation.

We did not really count one by one; otherwise, the pathology practice in every hospital will come to a halt.

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Q. Sir, would you expect to see increased lymphocytes, PMNs, macrophages, any of the inflammatory cells with the normal fallopian tubal tissue?

MS. MILLER: Objection.

THE WITNESS: It depends.

BY DR. RESTAINO:

Q. What does it depend upon?

A. If there is ectopic pregnancy, okay, you know, ectopic pregnancy in the fallopian tube, it is ruptured, and it will cause inflammation.

Q. Okay. That wouldn't be a normal fallopian slide, though, would it?

A. No, no, I would not review that.

Q. Okay. So I'll ask the question again. In comparing the inflammatory infiltrate that you define as lymphocytic, increased lymphocytic infiltrate, in comparing that with normal tissue --

A. What do you mean "normal tissue"?

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Q. The normal fallopian tissue.
A. Okay.
Q. NFT. Okay. So I believe I understood you that you said in one slide you look at the STIC lesion and you looked at the normal tissue; is that correct?
A. From the same specimen.
Q. Okay. And you compare the presence of the inflammatory lymphocytes around the STIC lesion, if there was any, with the normal tissue, correct?
A. For the same patients?
Q. Yes?
A. I did that way, yes.
Q. Now, why would you expect to see inflammatory cells around normal fallopian tissue if there is no disease process going on?
MS. MILLER: Objection.
THE WITNESS: I cannot understand your question. One more time.
BY DR. RESTAINO:

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Q. If you looked at the normal -- if you looked at the bottom slide, Number 59, 2004 NFT, with no concurrent cancer, no inflammation, you looked at the fallopian tube tissue and it's normal, you wouldn't expect to see increased lymphocytic cells, correct?
A. I did not see increased inflammation as compared to control.
Q. Which control?
A. Ovarian cancer.
Q. Okay. So now if you don't see increased inflammation around the normal fallopian tube, now you look at the STIC lesion to see if there's increased lymphocyte infiltrate, correct?
A. Yes.
Q. And you compare the two. How many lymphocytes are around the normal tissue, how many lymphocytes are around from the STIC lesion?
A. From the same specimen.
Q. Yes. Okay? Agreed? And that's what you did.

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MS. MILLER: Objection.
BY DR. RESTAINO:
Q. Now, if that lady was on Tagamet, you wouldn't expect to see a decrease in the normal fallopian tissue because they are not there. But you would expect to see decreased lymphocytes around the STIC lesion because that's what lymphopenia leads to, or corticosteroids lead to, are decreased inflammatory cells, correct?
MS. MILLER: Objection.
THE WITNESS: I think there's many typo errors. I cannot read this.
Could you repeat your question?
BY DR. RESTAINO:
Q. There are typo errors where?
MS. MILLER: He was trying to read the realtime and the realtime is -- because there are so many complicated words --
THE WITNESS: I think you

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speak too fast. I'm sorry. I -- even the specialist cannot understand what you are talking about. I'm sorry.
BY DR. RESTAINO:
Q. What I believe you did in this study, sir, was look at slides that were designated as having p53 signature lesions in them, or STIC, or cancer, and you compared the inflammation, if it was there, around those lesions, with normal tissue, correct?
MR. LOCKE: Objection.
BY DR. RESTAINO:
Q. Correct?
A. From the same patient?
Q. Whatever you did in this study. Whether it was in the same slide, or -- let me ask you this.
Why would you compare the number of lymphocytes around a STIC lesion in Patient A and compare her with the number of lymphocytes in Patient B?
A. Ah, okay. I think you are

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more clear now.
So this normal fallopian tubes without STICs, without cancer, it's just a control. It's not the point we want to study, okay. So I want to make sure that our -- my reference in pathology interpretation is correct. I use a normal fallopian tube that has been shown in the patient's medical record showing there's no evidence of morphologically remarkable lesions.
So if I see -- okay, just in case. If I see chronic inflammation in NFT by which in the medical record did not -- did show -- did not show that, then I need to have this serve as a calibration of my methodology and my methods. So it's as a control. Yeah. It's not the studies --
Q. I'm sorry.
So when you're comparing the noncontrol slide with the control, what do you know about that control -- the noncontrol slide's patient's medical

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history?
Did this patient have medical disorders leading to lymphocytopenia? Did this patient take medications that led to lymphocytopenia? You don't know that, do you, sir?
MS. MILLER: Objection. Asked and answered multiple times.
THE WITNESS: I already ask -- I already answered this question many, many times. Do you want me to repeat? I'm happy to.
BY DR. RESTAINO:
Q. I don't believe you've answered it. The record --
A. I do, I do. I do. Look at the transcript.
Q. The record will speak for itself.
A. Look at the transcript. Please look at the transcript.
DR. RESTAINO: Okay. Is lunch here? Shall we break for lunch at this point?

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MS. MILLER: I was going to try to push through till one, but we can quit now.
DR. RESTAINO: I can go -- ask a few more questions.
BY DR. RESTAINO:
Q. Now, sir, when did you start doing your study?
A. Which study?
Q. The study that we've been discussing all morning?
A. Again, this study, I would say this research project. Okay. So it's different. It's like STIC-like lesion and STIC, we have a different opinion, so that causes confusion in the previous transcript that come to my notice.
Q. Okay. If you pick up Exhibit Number 4.
A. Number 4.
Q. Which is your study report.
A. Yes.
Q. Okay. Look at the first

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page.
A. Yes.
Q. Time frame January 1st, 2019. On January 1st, New Year's Day, is that when you started some part of this study? What did you do, January 1st, 19 -- sorry. January 1st, 1953, is my birthday.
January 1st, 2019. What did you do on New Year's Day?
MS. MILLER: Objection.
THE WITNESS: I celebrate the new year.
BY DR. RESTAINO:
Q. Okay. What part -- what did you do for the study here on January 1st of 2019?
A. I start searching the eligible work cases.
Q. Okay. And at that point you were a retained expert for Johnson & Johnson?
A. Correct.
Q. Where in your study report

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do -- do you disclose that you're a paid litigation expert for Johnson & Johnson?
A. In this Exhibit 4?
Q. Yes.
A. This was not paid by J&J at all. I think this is our continuation of our research discovery, and we want to understand pathogenesis of ovarian cancer to help women.
Q. Okay. When you submit this paper for publication, do you not believe it's going to be required of you to disclose that you were an expert for Johnson & Johnson?
MS. MILLER: Objection. He never said that.
THE WITNESS: I'm distracted.
BY DR. RESTAINO:
Q. I'll ask it --
MS. MILLER: Sorry. I didn't mean to distract you.
BY DR. RESTAINO:
Q. I'll ask the question again,

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differently.
In the study report that you've attached to your expert report that you describe in your expert report as the full report, where is the disclosure?
A. I'm sorry --
MS. MILLER: Objection.
THE WITNESS: -- you say full report? This is not a full study yet.
BY DR. RESTAINO:
Q. Okay. Sir, we went through that before. And it's listed in your expert report wherein you state, "The full report is attached to the back of my expert report."
A. At that time, yes.
Q. Okay. So where in this report is your disclosure, your conflict of interest disclosure, that at the time you've been conducting this study you are a paid expert for Johnson & Johnson?
MS. MILLER: Objection.

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THE WITNESS: So if in my future manuscript submitted to the journal for the consideration of publication, if I talk about talcum powder, including Johnson & Johnson products, and I cite any reference -- references related to talcum powder, I will disclose it and I will say this study was not sponsored by J&J.
This is very, very important. This -- this is so-called ethics in publication. And like some study like Saed he did not disclose during the submission, which is totally trigger the suspicion of misconduct.
BY DR. RESTAINO:
Q. Did you -- did you review for your opinion that you just testified, his draft report or the final published article?
A. Both.

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Q. And in his final published article, does he state that he's a paid expert?
A. Can I have the reference to further discuss? Because I need to read whether he -- how he disclose it.
Q. It's listed in your expert report. As you sit here today, do you not recall how he -- how he lists --
A. I would like to see the documents. Do you have that? Dr. Saed? Dr. Saed's 2019? It is a really important point. I will show you the contrast, how I did it right.
Q. How you did it right? Where did you do it at all?
A. I'm sorry, sir?
Q. Where did you do it at all? Where in this full report did you disclose that you are an expert for Johnson & Johnson?
A. I was saying --
MS. MILLER: Objection. I've got to object to this. This

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report was attached to an expert report which has only been submitted to plaintiffs, who obviously know he is an expert.
This is just an incredibly unfair line of questioning.
THE WITNESS: I said I will disclose it when I submit to the journal editor for publication.
Okay. So this --
BY DR. RESTAINO:
Q. But your criticism of Dr. Saed was on his nonpublished draft. Did you -- did you look at his final published article with his declaration?
A. So the point is, as I serve in editorial boards to review many, many papers, and I also serve as editor-in-chief in a medical magazine, so whoever submitted for review, okay, it should be disclosed.
Do you know why? It's so important for the reviewers to judge whether there is any conflict of interest

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during the review process.
Q. Okay. Did Dr. Saed on his final published article declare the following potential conflicts of interest with respect to research, authorship, and/or publication to this article: "Dr. Saed has served as a paid consultant and expert witness in the talcum powder litigation"?
MS. MILLER: Objection.
BY DR. RESTAINO:
Q. Did he disclose that?
MS. MILLER: Objection.
Dr. Shih has asked multiple times could he see the study so he can answer the question accurately. And you're refusing to show it to him. If we go off the record, I can get a copy of it if you don't have it.
DR. RESTAINO: Why don't we just break for lunch, and we'll come back and he can take a look at it. Want to do that?

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MS. MILLER: Great.
THE WITNESS: Okay. Good.
THE VIDEOGRAPHER: The time is 1:01 p.m. we're going off the record.
- - -
(Lunch break.)
- - -
AFTERNOON SESSION
- - -
THE VIDEOGRAPHER: The time is 1:35 p.m. And we're back on the record.
- - -
EXAMINATION (Cont'd.)
- - -
BY DR. RESTAINO:
Q. Welcome back, Dr. Shih.
A. Thank you.
Q. When we broke, we were finishing up our discussion with the Dr. Saed, et al., study, correct?
A. Correct.
Q. And you asked to see the

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study. We were able to get a copy of it, which I'll now mark as exhibit next.
(Document marked for identification as Exhibit Shih-39.)
(Whereupon, a discussion was held off the record.)
BY DR. RESTAINO:
Q. Doctor, have you seen that publication before?
A. This publication?
Q. Yes, sir.
A. Yes, I did.
Q. And now if you would look at the Page 9 where the authors have their declaration of conflicting interests.
Do you see that, sir?
A. Yes.
Q. "The authors declared the following potential conflicts of interest with respect to research, authorship, and/or publication of this article." And, "Dr. Saed has served as a paid consultant and expert witness in the

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talcum powder litigation."
Did I read that correctly, sir?
A. Yes, they are showing in the paper.
Q. Sir, is it -- as you sit here today, having read that, is it still your opinion that Dr. Saed's disclosure is inadequate?
A. I believe this is inadequate because this disclosure need to be submitted in the time during the peer review process, because that's most important factor affecting the reviewers' opinion, whether -- how this study is supported and what other biased can be generated in this report.
I think it's really important. And as I reviewed his deposition I was provided by J&J law firm, and at that time, I don't see this statement. And also I learn from other expert reports, and I know that there is a serious problem because Dr. Saed

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testified that he was paid for writing this articles.
And as you know, this is a job for any academic professor or staff, that's their job, to write articles, because for their scientific discovery and exposure, rather than is supported by any parties outside of academic.
So I think clearly, as a editor-in-chief, I served that before, I will be really shocked about this late disclosure.
It did not cover up what has been done in the past during the review process. I think that's most important.
Q. Doctor, once published, this paper is available to the entire medical and scientific community to review, correct?
A. It was shown in PubMed and other search engines.
Q. And, therefore, any investigator desiring to read this article will pull the article and see

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that disclosure, correct?
MS. MILLER: Objection.
THE WITNESS: Can you say that one more time, slowly?
BY DR. RESTAINO:
Q. So any -- any investigator, any researcher, any physician, who pulls the article to review the article will see the disclosure that you're looking at, correct?
A. Correct.
Q. And the purpose of such a disclosure, is to allow then that reader to make up his or her own mind as for the potential of bias, correct?
A. I cannot agree, because the purpose of peer review system, as you know, is the theater that the publisher can select the good articles, no biased, no -- without any conflict of interest to present to the audience who did not know what happens before.
But this clearly is not the case, because there's two parts. One is

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a review process to determine whether this paper is -- is anything that's without conflict of interest. That's the first thing. Because it can severely affect the reviewer's mind. So when I have time to look at the first submission to Oncology, which was rejected, and then later in the Reproductive Science, then you can see there's a big difference in Reproductive Science.
There's only single review. And this is unusual in any review process, only allow for only one review.
And further, I can just reform the other opinions, that this really complicated relationship between the editorial office, authors, and I don't know what's going on. I don't have direct evidence.
But it's really -- I am so intrigued how this paper can be published. Omission -- this is junk science totally without any biological plausibility.

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DR. RESTAINO: I will strike -- move to strike the last statement as being unresponsive to the question.
BY DR. RESTAINO:
Q. Doctor, I just want to go over -- because in my mind I'm little a little bit confused about the chronology that we're dealing with. We discussed the grant that you have described in this paper and many other papers, the Department of Defense grant that you now say has expired, correct?
A. The funding has expired.
Q. If that began in 2014, is that -- is that what you testified?
A. Which one?
Q. Working with the grant?
A. The grant?
Q. Yes.
A. The DOD grant.
Q. Yes.
A. I think it's clearly marked in my CV. I can give you the specific

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date. Hold on a moment. It's very easy to find.
So on Page 34. "Prevention of Ovarian High-Grade Serous Carcinoma by Elucidating its Early Changes," W81XWH-11-2-0230. This is from October 1st, 2011.
Q. Okay. So in 2011, now you've published a number of papers utilizing the histopathology slides that come under the umbrella of that grant, correct, you have several publications?
A. I am not sure if it's a review paper or not reviews. I need to see which one you talk about.
Q. Just talking in general. Did you publish papers based upon the work that you've done under the auspices of this grant?
A. So as you know that the grant, we cannot only rely on one grant to publish something.
Q. Okay.
A. It is a network of grants,

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from this DOD, from different things, from private foundation, for my own funding, to come out with this. So you really can't -- you can delineate which parts use this grant. There's no way that I can delineate that for you, neither could any scientist can opine you.
Q. So now between 2011 and December 31st of 2018, the end of last year and that entire time, you did not consider conducting an experiment to look at the role of chronic inflammation and precursor cells associated with ovarian cancer; is that correct?
A. For which period of time?
Q. The entire period of time from December 31, 2018, back.
A. Actually, chronic inflammation is one of the -- many of the hypothesis. So of course we have an interest to look at that. So our first paper publish in -- in by Ardighieri as you -- you know about. That is the one

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that we publish as a best line, as a reference in the normal fallopian tube. What's the immune cell over there. Now this is a continuation of that.
Q. I'm sorry. I'm sorry. During that time --
A. Which time?
Q. The time period of the last few years, working and publishing papers, did you -- you were aware of the -- the controversy regarding talc powder and ovarian cancer, correct?
A. Between 2001 and --
Q. Between 2011 and December 31st of 2018. You were aware of the controversy, correct?
A. I heard from the news. But this is not my interest of research. I don't have any interest on that, because...
Q. But after meeting with the attorneys for Johnson & Johnson it became an interest of yours and then you started your study a couple of weeks later; is

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that correct?
MS. MILLER: Objection. I believe --
THE WITNESS: I'm interested in chronic inflammation. Okay. Chronic inflammation, not talc.
And in this study I did actually has nothing to do with talc. It's to do with chronic inflammation is present, absent or what happens associated with STIC and precursor signature. So this is not for the STIC litigation. It's part of a continuation of scientific curiosity. So it's not relevant.
BY DR. RESTAINO:
Q. In every publication dealing with chronic inflammation and ovarian cancer, prior to this interim report that we're now dealing with, you had co-authors working with you on every publication, correct?
MS. MILLER: Objection.

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THE WITNESS: I need to review the list, but I believe not all of them.
BY DR. RESTAINO:
Q. Have you published any paper that's not an editorial in which you did -- did not have co-authors?
A. So you meant single author in what kind of paper?
Q. Yes. You are the single author on this paper, correct?
MS. MILLER: Objection. I think that mischaracterizes his testimony earlier today.
THE WITNESS: We discussed that before. I said for the official publication we have not decided yet. I don't have time to think about what we want to come out with the research. It's a multiple research, or a single research, combined with molecular environment, molecular genetic, metabolomic, metagenetic.

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And as I said, we have no idea yet, because I cannot predict what happen next year.
BY DR. RESTAINO:
Q. So when you write in your expert report that this paper is the final answer regarding the chronic inflammation in precursor cells, what are we to take from that?
MS. MILLER: Objection. Can you point us to where he says that?
BY DR. RESTAINO:
Q. If you would look at the top -- first paragraph of Page 28 of his study report.
MS. MILLER: You said when you write in your expert report.
THE WITNESS: Expert reports?
MS. MILLER: Now, you are talking about the study reports?
DR. RESTAINO: The study reports.

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MS. MILLER: Okay. That was not the question.
Now, you said when you write in your expert report that this paper is the final answer, are you withdrawing that question?
DR. RESTAINO: I'm withdrawing that question.
BY DR. RESTAINO:
Q. So when you write in your study report, "So the final answer from this study is that ovarian cancer precursor lesions are not associated with chronic inflammation, thus refuting the hypothesis that chronic inflammation is the cause of ovarian cancer," that that would not be an accurate statement at this time, correct?
A. I'm sorry, I'm behind of you.
Q. Okay.
A. So where are you talking about, this page?
Q. Study report, Page 28. Top

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paragraph of 28.
A. Okay.
Q. Okay. And so the final -- the last sentence of that top paragraph on Page 28 states, "So, the final answer from this study is that ovarian cancer precursor lesions are not associated with chronic inflammation, thus refuting the hypothesis that chronic inflammation is the cause of ovarian cancer."
So, Doctor, you're making that statement in this study report based solely on your interim results, correct?
MS. MILLER: Objection.
THE WITNESS: This is the opinion I gave in this interim report.
BY DR. RESTAINO:
Q. Okay. Is that a litigation opinion?
A. Litigation opinion. What do you mean?
Q. I don't know, sir. You described the opinions of Dr. Saed and

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Dr. Kane in your expert report as litigation opinion.
What do you mean?
MS. MILLER: Objection.
THE WITNESS: I think that study was paid at least by writing by the company.
BY DR. RESTAINO:
Q. You think. What about Dr. Kane, the gynecological pathologist, why are her expert opinions litigation opinions and yours are not?
A. Can you show me what I say over that?
Q. Sure. Let's go now to the expert report.
A. Okay.
Q. And if you go to your page -- first page --
A. First page.
Q. -- Introduction of Scope of Report and Summary of Opinions.
Do you see that, sir?
Okay. And then your -- the

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third line down you write, "I was asked to review these litigation opinions and to assess their scientific validity."
So, sir, I have to ask you, what do you mean by litigation opinions?
A. Litigation opinions to me is to review the material provided to me, including deposition reports and their opinions.
Q. Okay. So in reviewing the deposition of Dr. Saed, to review Dr. Kane's report, Dr. Saed's report, and any other plaintiff expert you may have reviewed, is it fair and equal to say that your opinions that you're giving in your expert report and today are litigation opinions?
MS. MILLER: Objection.
THE WITNESS: It is my research opinion.
BY DR. RESTAINO:
Q. Is it your research opinion regarding the methodology that Dr. Kane utilized?

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MS. MILLER: Objection.
THE WITNESS: Those are two different questions.
BY DR. RESTAINO:
Q. Well, you have an opinion regarding Dr. Kane's methodology, correct?
A. Where did I say that?
Q. In your expert report.
A. Where? Where? I'm sorry.
Q. Oh, I'm sorry. Number 2 on that page, Dr. Saed's experimental results.
MS. MILLER: Are you talking about --
BY DR. RESTAINO:
Q. No, I'm sorry, Number 1. "Dr. Saed's and Dr. Kane's opinions related to biological plausibility of the theory that talc powder use can cause ovarian cancer or increase the risk of ovarian cancer are not the product of reliable methods and are contrary to established scientific knowledge."

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Doctor, what was Dr. Kane's methodology that, in your opinion, is unreliable?
A. You meant Dr. Saed and Dr. Kane together, or do you want me to separate?
Q. Let's separate. I want to talk --
A. Okay. All right.
Q. Dr. Kane's methodology, what about it was flawed?
A. I -- my opinion is she reached the conclusion by leaving many holes in between without showing any biological plausibility in the mechanism. Can I see that one?
MS. MILLER: What do you want? Dr. Kane's report?
THE WITNESS: Yeah, Dr. Kane report.
MS. MILLER: You have to ask them if they're okay with that.
THE WITNESS: Is that okay, that I can have a better

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discussion for that?
BY DR. RESTAINO:
Q. As you sit here today, can you tell us, without looking at your expert report, what are the flaws in what Dr. Kane utilized as her methodology?
MS. MILLER: I'm going to object to that, because as I recall at the beginning of the deposition, you said this was not a memory test.
THE WITNESS: Correct.
MS. MILLER: I mean, he addresses Dr. Kane in his report. Is he allowed to turn to where he addresses Dr. Kane --
DR. RESTAINO: Not if he's going to sit here with his finger going over every word in his report, because if so, we're going off the record.
BY DR. RESTAINO:
Q. Doctor, do you need to look at Dr. Kane's report to refresh your

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memory on the flaws in her methodology?
MS. MILLER: That's actually not what I said. I said may he look at his discussion of Dr. Kane's opinions without looking at Dr. Kane's report.
BY DR. RESTAINO:
Q. What do you need to look at to tell us what part of Dr. Kane's methodology was flawed?
A. It would be helpful to -- for me to review it.
Q. Review what, sir? Let me strike that question. Let me ask you this.
Did Dr. Kane conduct a systematic review of the literature?
MS. MILLER: Objection.
THE WITNESS: That, I don't know.
BY DR. RESTAINO:
Q. As you sit here today, what do you believe that Dr. Kane was basing her opinions upon?

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MS. MILLER: Objection.
THE WITNESS: From based on what I recalled, she did a literature search. I think she's a pathologist.
BY DR. RESTAINO:
Q. And pathologists don't know how to do literature researches?
A. I say she did literature search.
Q. As you did also, correct?
A. I'm not sure what does that mean, the same. We may use different key words and search engines. I don't know what she searched.
Q. So you're speculating on her methodology?
MS. MILLER: No, he's not speculating.
THE WITNESS: No, no.
MS. MILLER: You're refusing to give him the report.
THE WITNESS: Yeah.
MS. MILLER: He'd like to

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look at the report. He's not speculating. You're pressing him to answer without the report.
BY DR. RESTAINO:
Q. Do you need to see Dr. Kane's report?
A. If you have one, that would be great.
DR. RESTAINO: I don't even know if we have one.
BY DR. RESTAINO:
Q. If you assume that she used the same keywords, chronic inflammation, ovarian cancer -- you're shaking your head no.
A. No, I don't know what you -- what you meant. Could you speak slowly.
MS. MILLER: Shall we go off the record and get a copy of the report?
DR. RESTAINO: Sure.
THE WITNESS: I think that's the best way.
MS. MILLER: Okay. Let's go

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off.
THE VIDEOGRAPHER: The time is 1:56 p.m. We're going off the record.
(Short break.)
THE VIDEOGRAPHER: The time is 2:09 p.m. We're back on the record.
BY DR. RESTAINO:
Q. Doctor, during the break, did you have a chance to review Dr. Sarah Kane's expert report?
MS. MILLER: No, he didn't. As soon as I got it printed, I brought it in here. I don't think he had a chance. I mean, we got it printed, and I brought it.
BY DR. RESTAINO:
Q. Doctor, in your expert report, can you show me where you describe the flaws in Sarah Kane's methodology?
A. Sure. I think that's a fair question.

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In my report, Page 8, Number 3, Dr. Kane's opinions. And I should tell you that the methodologies Dr. Kane used has many, many flaws, just like Dr. Saed. And their opinions, the flawed opinions, share a lot.
So I can tell you Dr. Kane's incorrect methodology unique to her report first. Then we can go back to Saed because they overlap.
Q. What is it about her methodology that you find to be flawed?
A. Okay. Number 1, is showing in the Page 8, she claimed the lymphatic transport -- should I go over the sentences? I can do that.
Q. No. That's her opinion, isn't it?
A. Right. So I can show you.
Q. I'm asking you, as to her methodology to get to her opinions, what about her methodology was flawed?
MS. MILLER: Objection.
THE WITNESS: She reached

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her conclusion, which is incorrect, based on those reports. But that's her misinterpretation of the result. And there's many holes in between that prevent her to come to a conclusion.
For example, the lymphatic transport, the similarity between talc structure and asbestos, and also she confused mesothelioma and high grade serous carcinoma. And that's based on her search.
And then she claimed that the talc is causal for ovarian cancer, in which the methodology is totally flawed, and there is no biological plausibility.
As an example, I think she is a pathologist. She knows what's the difference between mesothelioma and high grade serous carcinoma, and she claim that based on her experience that these two are very similar.

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But it's not. They are not. Every well -- every trained, I'm sorry, every trained board-certified pathologist can tell them apart. They are so different, not only in morphology, their pathogenesis and the clinical outcome, they are different.

That's one. I think that she did not have a correct methodology in that opinion.

The other one is the lymphatic spread --

BY DR. RESTAINO:

Q. Okay. Let's go over the first one there.

A. Okay. Okay. All right.

Q. We'll get too far ahead of ourselves. Okay? Regarding the -- or you believe that she has a flawed opinion regarding how the human body will react to different stimulus. If the -- if the talc is absorbed in the lympathic system

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and -- and goes throughout the body, correct?

MS. MILLER: Objection. I don't think that was what he said.

BY DR. RESTAINO:

Q. Well, to -- to read what you -- to read what you say about lympathic transport. "If talc particles can travel through the lympathic channel to the ovaries, they should be able to reach other human body parts and tissues as well, because the lympathic system runs throughout the body. There are no reports showing that talc is associated with other types of female (or male) cancer like colon cancer, liver cancer, stomach cancer, prostate cancer, and pancreatic cancer (where lympathic circulation is active) just to name a few."

Okay. Now, Doctor, is it your expert opinion that all tissue in the human body will react the same way to the same stimulus?

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A. It depends. It depends on what kind of tissues you are talking about and the concentration of the talc powders.

Q. Therefore, not all body tissues are going to respond the same to an external stimulus, correct?

MR. LOCKE: Objection.

THE WITNESS: But if the concentration is the same, the patients respond in a similar way.

BY DR. RESTAINO:

Q. Okay. Have you heard of the bacterium Helicobacter pylori or H. pylori?

MS. MILLER: Objection.

THE WITNESS: Yes.

BY DR. RESTAINO:

Q. Yes. It's known to cause stomach adenocarcinoma, correct?

A. It cause peptic ulcer and chronic inflammation.

Q. And hepatic carcinoma, correct?

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A. That's everybody believe.

Q. Everybody -- in fact, IARC lists H. pylori as a Class I carcinogen, does it not?

MS. MILLER: Objection.

THE WITNESS: I don't have the documents with me.

BY DR. RESTAINO:

Q. And H. pylori is -- it is contracted typically orally, correct?

MS. MILLER: Objection.

THE WITNESS: I'm a pathologist, and a cancer biologist and not gastroenterologist.

BY DR. RESTAINO:

Q. Does the H. pylori travel through the mouth and esophagus to get to the stomach?

A. I'm not a microbiologist either.

Q. Okay. Does the -- are the -- are you aware of any reports of H. pylori causing tongue cancer?

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A. Again, I'm not the H. pylori specialist.
Q. Does it cause upper esophageal cancer?
A. I'm a gynecology pathologist. We only care about below diaphragm.
Q. Okay. So you don't know if those tissues react differently to that external stimulus, correct?
A. It's outside my opinion.
Q. Certain strains of human papilloma virus or HPV are generally accepted to cause cervical, vaginal, vulvar, penile and oropharyngeal cancer, correct?
A. Can you show me the evidence?
Q. Are you not aware of what forms of cancer H. papilloma virus cause?
A. H. pylori? Not HPV, right?
Q. Human papilloma virus.
A. Okay.
Q. HPV.

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A. HPV. I think you said H. pylori or --
Q. Okay. I'll strike the question and I'll ask it over again.
Certain strains of human papilloma virus, HPV, generally accepted to cause cervical, vaginal, vulvar -- vulvar, penile and oropharyngeal cancers, correct?
A. I think it has been shown in many articles.
Q. But they are not known to cause cancers of the upper reproductive tract, are they?
A. Upper reproductive, meaning from which organs?
Q. As a pathologist, what do you -- what organs do you classify as being of the upper reproductive tract?
MS. MILLER: Objection.
BY DR. RESTAINO:
Q. I want to use the organs you are most comfortable with, sir.
MS. MILLER: Is that a

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question?
THE WITNESS: How is this relevant to -- to my role as a cancer biologist in this case?
BY DR. RESTAINO:
Q. You are offering an opinion that Dr. Kane's opinion regarding lympathic transport is different and you're using an example of why it doesn't cause cancer or problems in other body parts. There you are an expert; is that correct?
MS. MILLER: Objection. Argumentive.
THE WITNESS: The lymphatic transport of talcum powder as Dr. Kane opined in the -- the lymphatic system and the lymph node, this is not relevant to tubal -- okay. STIC and precursor signatures.
Because in the fallopian tube there is no lymph nodes.
BY DR. RESTAINO:

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Q. Doctor.
A. Yeah.
Q. In your critique of Dr. Kane's opinions, it is true, is it not, that different body tissues react differently to different stimuli, correct? The esophagus does not react to H. pylori, the antrum of the stomach does, correct?
A. There is no evidence to show the esophageal cancer at this moment. But I don't know whether it will be shown in the future years.
Q. And you don't know whether it's going to be shown in the future years or whether talc is transported through the lympathic system to the pelvic lymph nodes where it could cause a problem, or are you aware of a publication this week on talc migrating to the pelvic lymph nodes? Are you aware of that publication, sir?
MR. LOCKE: Objection.
MS. MILLER: Objection.

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That was like seven different questions.
THE WITNESS: I think I'm distracted by your different questions so --
BY DR. RESTAINO:
Q. I'll strike that --
A. How is it relevant to -- to the -- to the Dr. Kane's opinion?
Q. Okay. You don't understand it; is that right?
A. I don't know how relevant those questions that is -- that I can help you to answer.
Q. Okay. How about hepatitis C, that's a bloodborne pathogen, correct?
A. Yes.
Q. Gets in the blood. So therefore, by definition it goes throughout the entire human body, correct?
A. Right.
Q. And hepatitis C form --

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causes what form of cancer?
A. Liver cancer.
Q. It goes through all the different organs to get to the liver, correct, but it doesn't cause cancer in those other organs, right?
A. That's hepatitis C itself.
Q. Yes.
A. But it cannot be extrapolated to other agents. Every agent are different.
Q. Okay. Like H. pylori only affects the stomach, right? It's spreading and each body tissue is acting differently.
Let's go and talk about the chemical similarities --
MS. MILLER: Is that a question?
THE WITNESS: No, that is not a question.
BY DR. RESTAINO:
Q. No. I'm moving on to Page 9 now of your expert report. You talk

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about, you criticize Dr. Kane for talking about chemical similarities between asbestos and talc, correct?
A. I talk about that.
Q. Yes. Now, when you were taking, as a student way back when, you took organic chemistry, correct?
A. I did not teach organic chemistry.
Q. Did you take it as a student?
A. Many, many years ago.
Q. I understand. Now, when you were taking chemistry, did you study the structural composition of various components, various chemicals, minerals, whatever, when you were taking organic or inorganic chemistry, you studied the structure of those compounds, correct, even water, H2O, did you study that analysis, that structure?
MS. MILLER: Hey, can we try to stick to one question at a time?

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DR. RESTAINO: Yes, I'm sorry.
THE WITNESS: So --
MS. MILLER: I know you were getting excited, but I don't know that we understand what the question is.
THE WITNESS: You were asking about water. Okay. I can answer -- answer you any water questions, can I? I don't know what kind of question of water in the biophysics and bioengineering and biochemistry.
BY DR. RESTAINO:
Q. There's a structure to water of two hydrogen atoms and an oxygen atom, correct?
A. Yes.
Q. Okay. So you are looking at -- studying the chemistry of water, you're looking at the structure of it, correct?
MS. MILLER: Objection.

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I'm sorry.
THE WITNESS: I cannot remember what I took, the content in my organic chemistry back to many, many years ago.
BY DR. RESTAINO:
Q. Doctor, is there a difference in your mind between the chemical structure of talc and asbestos or the structural structure?
MS. MILLER: Objection.
THE WITNESS: Structure of the --
MS. MILLER: Structural structure?
THE WITNESS: I'm not a mineralogist.
BY DR. RESTAINO:
Q. You are not a -- but you criticize Dr. Kane for saying that there were chemical similarities between asbestos and talc, correct?
A. I use my general opinions to show that structural similarity. It

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doesn't mean that they are the same, carry the same effect on human tissue. That's why I'm going to say very general things. Okay. You -- if you want to ask me what's the really difference, oxygen and the bindings, I'm not -- it's outside my expertise and my opinion.
Q. It is your opinion, though, that both talc and asbestos have structural similarity to some degree. Talc is not asbestos; is that correct?
MS. MILLER: Are you reading a sentence from here?
DR. RESTAINO: It's middle of the large paragraph on Page 9 of the report.
THE WITNESS: Okay.
BY DR. RESTAINO:
Q. "Therefore, both" -- "although both talc and asbestos have structural similarity to some degree."
Do you see that, sir?
A. Yes.
Q. And that's what Dr. Kane

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said, correct?
MS. MILLER: Objection. Can you show him where Dr. Kane says that?
THE WITNESS: Right. I need to have a close comparison. I'm not sure that's what Dr. Kane said.
BY DR. RESTAINO:
Q. Okay.
A. Could you have that line of -- and we can compare.
Q. In your report, don't you criticize on Page 5 of the report that --
A. Page 5?
Q. Your expert report. I believe it's Page 5, and that's where you write, "There are chemical similarities between asbestos and talc, and there are striking pathological similarities between invasive serous ovarian cancer and mesothelioma."
And you criticize Dr. Kane for saying that there's chemical -- that

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there aren't not chemical similarities, don't you?
A. I'm sorry. I'm so confused. You're jumping 9 and 5 and which section are you talking about? We are talking about Dr. Kane's opinion or my report?
MS. MILLER: I'm not seeing anything on Page 5 that you just read. Page 5 is Dr. Saed.
THE WITNESS: Right.
MS. MILLER: So I'm really confused.
THE WITNESS: I cannot see the arguments.
DR. RESTAINO: Okay. Give me one second then.
MS. MILLER: On Page 8 he quotes Dr. --
BY DR. RESTAINO:
Q. On Page 9 of your expert report.
A. Okay. Page 9.
Q. Okay. You have in quotation marks, "Chemical similarities between

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asbestos and talc," do you not?
Page 9 of your expert report.
MS. MILLER: That's quoting Dr. Kane, who he quotes in full on Page 8.
DR. RESTAINO: Yes. I want to get him to say on the record that's Dr. Kane's words.
THE WITNESS: That's Page 8?
BY DR. RESTAINO:
Q. Page 9. You have a paragraph that's titled, "Chemical Similarities Between Asbestos and Talc," correct?
A. Yes.
Q. And then you say, "This is incorrect."
What -- do you see where I am?
A. Yeah.
Q. Okay. So my question, I was talking to you before about the chemical similarities, you state -- your opinion

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is that there are structural similarities, correct?
A. No. This is quote from Dr. Kane. I did not say that.
Q. You write the next sentence, "Structural similarity of chemical compounds does not mean they have the same function or effects."
Correct?
A. "This structural similarity," in the second line, is referring to Dr. Kane's quotes, "Chemical similarity between asbestos and talc." That's her opinion, not my opinion.
Q. Now, what Dr. Kane in her report was -- are you familiar with the Bradford Hill viewpoint of analogy?
A. Could you show me the Bradford Hill?
Q. Do you not know -- you are not aware of using analogy to determine causation?
A. But that's back to 1965 when the science is really arcane and there is

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no biological plausibility -- I mean, the methodologies and the techniques for confirming -- not confirming, I'm sorry, strike that out -- to support the evidence that something is A or B or C. So at the time, meaning the technology, we don't have that yet.
Q. So is it your opinion sitting here today, that it's no longer a valid scientific question to look at and see whether two compounds are analogous to one another in their effect on the body?
MS. MILLER: Objection.
THE WITNESS: Oh, this is really big questions. It's so general. There's many questions embedded in your question. Can you specify them as specific as possible?
BY DR. RESTAINO:
Q. Is it your opinion that it's no longer scientifically valid to consider analogy when looking at a causal

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question?
MS. MILLER: Objection.
THE WITNESS: It depends.
BY DR. RESTAINO:
Q. Okay. So Dr. Kane, when she's looking at talc and asbestos and making an analogy with them, is that an improper methodology for her to employ?
MS. MILLER: Objection.
THE WITNESS: It's incorrect methodology in this specific case, because asbestos is different from talc.
BY DR. RESTAINO:
Q. Have you asked any representative of Johnson & Johnson to provide you with any documentation they have on the similarity between talc and asbestos?
MS. MILLER: Objection.
THE WITNESS: I do not recall.
BY DR. RESTAINO:
Q. Did anyone from Johnson &

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Johnson provide you with any documentation that they have on the similarity between talcum powder and asbestos?
MS. MILLER: Objection. Lacks foundation.
THE WITNESS: This is not relevant to my reason to be here today. I'm here to testify biological plausibility and molecular mechanism together with gynecology and pathology to determine there's no biological plausibility. Everything is not credible science and the full technology in this case. Period.
DR. RESTAINO: Move to strike as unresponsive.
BY DR. RESTAINO:
Q. Did anyone from Johnson & Johnson provide you with any documentation they may have on the similarity between talc and asbestos?
A. I think I already answered

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your question. This is not relevant to my position here.
Q. It's a yes or no question, Doctor. Did anyone give you any documentation that Johnson & Johnson may have on the similarities between talc and asbestos?
MS. MILLER: Same objection.
MS. SHARKO: Mr. Restaino, I don't believe that any company documents were supplied to Dr. Shih if that is helpful.
DR. RESTAINO: I'll proceed with your representation.
THE WITNESS: I don't know that. Yeah.
MS. MILLER: Anything that we provided him would be on his reliance list, which you have.
BY DR. RESTAINO:
Q. Do you understand that Johnson & Johnson has admitted that asbestos has been in their talcum powder products in the past?

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MS. MILLER: Objection.
MR. LOCKE: Objection.
MR. MIZGALA: Objection.
MS. MILLER: Three objections at once. I think they call that a jinx. Kids. I don't know if they still do that.
THE WITNESS: I don't know.
MS. MILLER: In my day they called it a jinx.
BY DR. RESTAINO:
Q. Had you -- have you reviewed the deposition of any Johnson & Johnson mineralogist?
MS. MILLER: Objection. As I said, anything that he has reviewed would be on his list, so...
BY DR. RESTAINO:
Q. Have you reviewed any --
A. As I said, I reviewed whatever had been provided.
Q. So, Doctor, when you are approaching this now from your area of

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expertise, as is Dr. Kane, is there a difference between disagreeing with her methodology and disagreeing with her conclusions?
MS. MILLER: Objection.
THE WITNESS: Her methodology is flawed, and her conclusion is coming from nowhere.
BY DR. RESTAINO:
Q. Where in your expert report does it discuss her methodology and why it's flawed?
A. You mean Dr. Kane specifically, right?
Q. Yes.
A. So as we discussed, there are many thing that overlap with Dr. Saed. So I would start from the -- really the beginning.
Number one -- can I have the report so I can refer to the figures tables, Dr. Kane's? Or you don't need that?
Q. No, the question is where in

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your expert report do you discuss her methodology.
A. In -- okay. Page 8 and Page 9 specifically, but there are also overlap opinions against her in other pages, like Page 5 and I believe on Page 4, 5 -- I should say Page 4, 5, 6, 7, 8 and 9.
Q. What I see on each of them, Doctor, is, in fact, for example, if you go to Page 8, you have a Number 3, Dr. Kane's opinions, correct?
A. Right.
Q. Where is your description of how she got to those opinions which in your opinion is flawed?
MS. MILLER: Objection --
BY DR. RESTAINO:
Q. Where is -- I'm sorry. Where is the description of her methodology?
MS. MILLER: -- methodology. Could we start over because that is confusing. That was different

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questions.
What is your question?
THE WITNESS: So it should --
BY DR. RESTAINO:
Q. Listed here is Dr. Kane's opinions. Where is your description in your expert report of the -- of the methodology employed and why in your opinion it was flawed?
MS. MILLER: Objection.
THE WITNESS: She had -- she had several opinions like Dr. Saed for example. Like ROS, reactive oxygen trace --
BY DR. RESTAINO:
Q. I'm going to move to strike.
Doctor, I understand, sir, respectfully, I understand that you disagree with her opinions. I'm asking, where is your analysis of the method she employed to get to her opinion.
MS. MILLER: Objection.
THE WITNESS: So I would say

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that the literatures I reviews, and based on my credential, as you can see my CV, and I review so many papers, publish so many papers, and with more than 32,000 citations, that's my expertise, and I can judge as an authority in ovarian cancer biology field that her methodology is flawed.
And I already expressed my concern in -- in this report.
BY DR. RESTAINO:
Q. Doctor, other than disagreeing with her opinions, where in your expert report do you describe what methodology Dr. Kane used and why that methodology is flawed?
MS. MILLER: Objection.
THE WITNESS: Her methodology is based on the literature she reviewed, and the jump into the conclusion. But there is many things that should not prevent this jumping style

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conclusion.
So her conclusion is based on no credible science and the cogent evidence at all. So her entire methodology she used is wrong, because you jump around.
BY DR. RESTAINO:
Q. What methodology did she use?
MS. MILLER: Objection.
THE WITNESS: The methodology is like -- okay. So this is the difference between Dr. Kane and me. So it's very difficult to prove negative.
So if this is a case Dr. -- Dr. Kane and -- or Dr. Saed propose that talcum powder can cause ovarian cancer, you need to show evidence.
So again, this is very important. Science is evidence driven. Evidence is held --
BY DR. RESTAINO:

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Q. Doctor, with all due respect, sir. I'm going to move to strike.
MS. MILLER: Well, you asked what methodology she used and he was trying to explain that.
THE WITNESS: Yeah, that's my -- that's my --
MS. MILLER: I think that actually he was answering your question fairly.
THE WITNESS: Right. So that's my -- my methodology.
MS. MILLER: He's trying to explain the difference between his methodology and her methodology.
THE WITNESS: Right. My methodology is different from her role. Her role is to demonstrate the evidence positive. Okay. My methodology, I cannot find any positive credible science, cogent evidence that can support the biological mechanism of talc can

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induce ovarian cancer. So her methodology, I -- totally is wrong, okay, because she cannot prove that, or she cannot provide evidence for biological plausibility.
BY DR. RESTAINO:
Q. Doctor, is there -- it is your opinion, is it not, that there is no evidence that talcum powder causes ovarian cancer, correct?
MS. MILLER: Objection. Can you point to where he said that?
BY DR. RESTAINO:
Q. Is that your opinion, Doctor?
A. Do you know where -- where is in the -- in my reports? Could you show me line and the page?
Q. Well, first in your testimony today, you said my methodology, I cannot find any positive credible science, cogent evidence, that support the biological mechanism of talc can

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induce ovarian cancer.
Is that correct? That's what you just said.
A. Yes, I did.
Q. Okay. Now, you are the -- you are -- is it your position that the Kimmel Center, is that you are the director or co-director?
A. I'm co-director.
Q. You are the director?
A. Co-director.
Q. Co-director. I'm sorry, sir.
A. Of breast and ovarian cancer program.
Q. Okay.
A. Okay.
DR. RESTAINO: I'd like to have marked as -- it's already marked.
(Document marked for identification as Exhibit Shih-8.)
BY DR. RESTAINO:

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Q. Exhibit 8, a copy of the website from the Sidney Kimmel Comprehensive Cancer Center.
Do you see that, sir?
Do you see at the top it says Johns Hopkins University, Sidney Kimmel Comprehensive Cancer Center, correct?
A. Yes.
Q. And on the bottom of that page, above age, it says, "Ovarian cancer risk factors."
Do you see that, sir?
A. Can I take a minute to see what's this about, because this is the first time I ever see.
Q. You don't know what her own website says -- states?
A. No, we -- I do not maintain a website. I do research.
Q. Okay. Well, if you turn to the bottom of the second page, do you see where they list there, talcum powder and asbestos?

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A. Where?
Q. Page two at the bottom, talcum powder and asbestos.
Do you see that, sir?
A. "Habitual use of talcum powder on the genital area may" -- "may increase the risk of ovarian cancer, but the evidence is not strong."
Q. But there's evidence. You just stated that there was no evidence. Your website says the evidence is not strong?
MS. MILLER: That misstates his testimony. And you read his testimony. His evidence was about biological plausibility. I mean, this is the second time you're misstating his testimony.
BY DR. RESTAINO:
Q. Do you agree, Doctor, that there is evidence linking talcum powder with ovarian cancer?
MS. MILLER: Objection.
THE WITNESS: There is no

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credible science and cogent evidence to support the biological plausibility of talcum powder can induce ovarian cancer.
BY DR. RESTAINO:
Q. Why would it not -- why would it say that on the website if there was no biological plausible evidence?
A. When you see this, it say "may increase," okay. Then, "The evidence is not strong," but this is -- this is not the word that we use here. And also you can say -- you can see in the following sentence, okay -- from my view, this is totally hypothetical. There's no biological evidence to support biological plausibility and the mechanism at all.
Q. And you're looking at the epidemiological evidence also, correct?
MS. MILLER: Objection.
What do you mean by that?
THE WITNESS: So review, what do you mean I review? I

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review everyone? Or what?
MS. MILLER: I don't understand the question.
THE WITNESS: I don't understand. Yeah, I can't understand.
BY DR. RESTAINO:
Q. In your review to make the determination that you do not find any evidence -- "I did not find any evidence molecular, biological, pathological, or epidemiological in nature that supports the conclusion that talc can cause or increase risk of ovarian cancer."
Now do you understand what I mean by epidemiological evidence?
A. Could you show me where --
Q. Your Opinion Number 3. Take a look at your expert report. First page. Opinion Number 3.
A. Which?
Q. Number 3, "Based on the recent research findings as published, I did not find any evidence" --

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A. Hold on. Hold on. I do not see that. Page 3?
Q. No, first page.
A. First page.
Q. Opinion Number 3.
A. Okay.
Q. "Based on the recent research findings as published, I did not find any evidence -- molecular, biological, pathological or epidemiological in nature -- that supports the conclusion that talc can cause or increase the risk of ovarian cancer."
Did I read that correctly?
A. This has been written in my report.
Q. Yes. Now, in the website for Sidney Kimmel Cancer Center, it states that there is evidence, although it's not strong, correct?
MS. MILLER: Objection.
That misstates what the website says.

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THE WITNESS: I don't know who wrote this. This is not from me. So I cannot comment on that.
BY DR. RESTAINO:
Q. Okay. As part of your work to -- for your opinions in your expert report, you looked at the epidemiology of chronic inflammation and the development of cancer?
MS. MILLER: Objection.
THE WITNESS: Again, I'm not an epidemiologist. But I review, quickly scan several articles in epidemiology field --
BY DR. RESTAINO:
Q. Okay. Including --
A. -- to come to my conclusion, not based on single, not based on single individual reports.
Q. Doctor, before we move on to this study, I want to discuss with you your Opinion Number 3 on the first page of your report.
A. Can you read it? Are we on

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the same page?
Q. Opinion Number 3 on the first page, the same one we were just looking at.
Did you write that opinion?
A. You mean starting from, "Based on recent research findings"?
Q. Yes.
A. "As published."
Q. Did you write that?
A. Yes.
Q. No one else helped you with any part of your report?
A. I don't think so.
Q. You don't think so, or you know so?
A. There's nobody to help me.
Q. Nobody else?
A. Yes.
Q. Okay.
(Document marked for identification as Exhibit Shih-10.)
BY DR. RESTAINO:

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Q. Doctor, I just handed you a paper by Trabert, T-R-A-B-E-R-T.
MS. MILLER: No, it's fine. I have that online. I think I have the same study.
BY DR. RESTAINO:
Q. The title of it is "Prediagnostic Serum Levels of Inflammation Markers and Risk of Ovarian Cancer in the Prostate, Lung, Colorectal and Ovarian Cancer (PLCO) Screening Trial."
Did I read that correctly?
A. That's the title.
Q. Yes. And this study is not referenced in your expert report, is it?
A. Yes, it's not listed.
Q. And this paper was published in Gynecologic Oncology in 2014, correct? The citation is right above the title.
Do you see that, sir?
A. Yes, I do.
Q. Do you recognize that as being Gynecological Oncology, 2014,

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November, correct?
A. Yes. 135, Page 297, yes.
Q. Okay. Now, in the title we're dealing with inflammation markers and the risk of ovarian cancer, correct?
A. That was written down in the title.
Q. Okay. Now, if one was conducting -- such as yourself, conducting a review of the literature after 2014 using keywords "inflammation" and "ovarian cancer," one should find this article, correct?
A. That's a hypothetical. How can you know that we have come up with this one?
Q. Okay. When you conducted your literature search utilizing the keywords ovarian cancer and inflammation, did you find this article?
A. I cannot recall. But I did -- I pull out those references, the most relevant, and provide biological plausibility or mechanism. Then I will

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take a look and cite it. But this one is -- it's junk science. It did not tell you anything about biological plausibility.
Q. What are you referring to?
A. This paper.
Q. How do you know that if you haven't even looked at the paper?
A. Now I remember. I saw this paper.
MS. MILLER: This paper is on his supplemental reliance list produced yesterday, sir.
THE WITNESS: Yeah, I remember that I saw this.
MS. MILLER: I don't know if you noticed.
BY DR. RESTAINO:
Q. So you remember -- so you have reviewed this?
MS. MILLER: He never said he hadn't.
BY DR. RESTAINO:
Q. Okay. Now --

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MS. MILLER: If you look at his supplemental reliance list, it was listed on there.
BY DR. RESTAINO:
Q. Okay. Now, sir, each of these authors are with the National Cancer Institute, correct?
A. I need to double-check.
Division of Cancer Epidemiology, National -- NCI -- NIH, HPV Immunology, Frederick National Laboratory for Cancer Research, National Cancer Institute, National Institute of Health Department of Health Human Service, Frederick, Division of Cancer Prevention, National Cancer Institute, National Institute of Health.
MS. MILLER: If you're going to read to yourself, you need to read to yourself.
THE WITNESS: Correct. You are totally correct. They are for NIH.
BY DR. RESTAINO:

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Q. And none of these individuals are experts in the talcum powder litigation, correct?
A. I don't know.
Q. Do you know if -- if members of the NCI are allowed to work in legal controversies such as this?
A. This is beyond my expert.
Q. Okay. Fair enough. Fair enough.
Turn to the introduction on Page 1 which is the next -- or it's actually Page 2, the next page. Introduction.
Do you see that, sir?
A. Yes.
Q. Very first paragraph under the word introduction states, "Epidemiological evidence implicates chronic inflammation as a central mechanism in the pathogenesis of ovarian cancer, the most lethal gynecologic cancer among women in the United States. Reference 1."

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Did I read that correctly?
A. That's the words in this paper.
Q. I'm sorry?
A. That's the words put in the paper.
Q. The wart?
A. The words. The words.
MS. MILLER: Words.
BY DR. RESTAINO:
Q. Words, okay. In the paper, correct?
A. Yes. It is words. Just words.
Q. Okay. Now, if you turn and you look at reference Number 1, in the back, on Page 9, are you there, sir?
A. Yes.
Q. The authors from the National Cancer Institute are referencing the Centers For Disease Control and Prevention, ovarian cancer statistics. 2010, correct?
A. That's what was cited.

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Q. Okay. And the Centers For Disease Control and Prevention, they are known as the CDC, would you agree?
A. Agree.
Q. So we've got authors from the NCI referencing the CDC, correct?
A. As it appears.
Q. Okay. Now I want to break down that first sentence for you, sir. It has two parts.
First part is, "Epidemiologic evidence implicates chronic inflammation as a central mechanism in the pathogenesis of ovarian cancer."
Do you see that -- that verbiage, sir?
A. As it has been written in this way.
Q. Okay. Do you have any objective evidence to contradict that statement?
MS. MILLER: Objection.
THE WITNESS: Your statement

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or this statement, or --
BY DR. RESTAINO:
Q. The statement "epidemiologic evidence implicates chronic inflammation as a central mechanism in the pathogenesis of ovarian cancer."
A. So this is the first sentence you are referring to, right?
Q. Yes, sir.
A. Do you know how many sentences in this article?
Q. Sir, I'm just asking if you agree with these authors from the NCI when they write, "Epidemiologic evidence implicates chronic inflammation as a central mechanism in the pathogenesis of ovarian cancer."
Do you disagree with that?
MS. MILLER: Objection.
THE WITNESS: I don't know any credible science and cogent evidence to show chronic inflammation can cause ovarian cancer. And I don't know which

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type of ovarian cancer they are talking about in this paper. High grade serous, low grade serous, endometriosis, carcinoma, sarcoma, I don't know.
So this one is too vague.
BY DR. RESTAINO:
Q. Do you think -- do you think the researchers from the National Cancer Institute know the difference?
MS. MILLER: Objection. Calls for speculation.
DR. RESTAINO: I'll withdraw it.
BY DR. RESTAINO:
Q. Doctor, can a reasonable scientist agree with the statement, "Epidemiologic evidence implicates chronic inflammation as a central mechanism in the pathogenesis of ovarian cancer"?
MS. MILLER: Objection.
THE WITNESS: They -- no, they should not. Because there is

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no credible science, cogent evidence to support biological plausibility. If it's epidemiology, it's epidemiology. If it's an association study, association is not causal. So I think that's a key point.
Association. It's just association. So many things can be associated with something.
BY DR. RESTAINO:
Q. So, Doctor, is it your opinion that these authors from the National Cancer Institute publishing in Gynecological Oncology are not reasonable scientists?
MS. MILLER: Objection.
THE WITNESS: I view the science not by the authors or their institutions or the journal they published. I am a scientist. I think I am a good scientist. Probably one of the best scientists in gynecology fields,

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okay.
So that's why we did.
That's why we teach students, based on the science. If it's good science, it's good science. If it's bad science, it just don't support at all. Don't even create any anything to --
DR. RESTAINO: I move to strike as unresponsive.
BY DR. RESTAINO:
Q. Doctor, can a reasonable scientist agree with the scientists from the National Cancer Institute when they publish in Gynecologic Oncology and reference the CDC, is it reasonable for a scientist to rely upon that?
MS. MILLER: Objection.
MR. LOCKE: Objection.
MS. MILLER: That is just objectionable in so many ways, I won't go into them. I don't want to get in trouble for too many speaking objections that Michelle

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doesn't like.
THE WITNESS: I think my answer can apply to this question too. So I don't need to reiterate.
BY DR. RESTAINO:
Q. Okay. Let's look at the next sentence.
A. Okay.
Q. "Chronic inflammation can induce rapid cell division, increasing the possibility for replication error, ineffective DNA repair and subsequent mutation."
Did I read that correctly?
A. It has been written in this way.
Q. Okay. And do you have any objective evidence to contradict the NCI researchers when they state that chronic inflammation can induce rapid cell division?
MS. MILLER: Objection.
THE WITNESS: Where is the

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citation for this statement?
DR. RESTAINO: Move to strike as unresponsive.
BY DR. RESTAINO:
Q. Doctor, from your knowledge as a pathologist, okay, just using that alone, rapid cell division increases the possibility for replication error, does it not?
MS. MILLER: Objection.
THE WITNESS: As a scientist, probably one of the best scientists in this field, I only trust the evidence, not based on whatever, whoever talk about this.
I need to see the evidence. Where is the citation?
BY DR. RESTAINO:
Q. Have you -- have you ever seen evidence that chronic inflammation induces rapid cell division? That's common pathological physiology, is it not, sir?

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A. It depends on the --
MS. MILLER: Objection. Hold on, Dr. Shih, let me object.
THE WITNESS: Okay. I'm sorry.
MS. MILLER: There were two questions there. Which one do you want him to answer?
THE WITNESS: Right.
BY DR. RESTAINO:
Q. Do you agree chronic inflammation can induce rapid cell division?
A. That's too general. It depends on the tissue type, your severity of chronic inflammation, the patient's immunity, and also the defense mechanism and also circulation, ischemic status, and many things.
Q. Can a reasonable scientist agree that chronic inflammation induces rapid cell division in carcinogenicity?
A. No. I don't see any evidence for that though.

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Q. Okay. Can a reasonable scientist agree that rapid cell division increases the possibility of replication error?
MS. MILLER: Objection. Agree with what?
DR. RESTAINO: Who it's from --
THE WITNESS: Who say that? Who say that statement? Who are the scientists and --
BY DR. RESTAINO:
Q. The researchers from the NCI. We just read it. I'll read it again for you. Please keep this in your mind, Doctor.
"Chronic inflammation can induce rapid cell division increasing the possibility for replication error, ineffective DNA repair, and subsequent mutations written by researchers from the National Cancer Institute, published in the peer reviewed publication Gynecologic Oncology 2014."

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Doctor, can a reasonable scientist agree with these scientists from the NCI when they state that chronic inflammation can induce rapid cell division?
MS. MILLER: Objection.
THE WITNESS: There is no credible science and cogent evidence to show that chronic inflammation, where two of those things envelop into epithelial cells, which is irrelevant to ovarian cancer -- I mean, high grade serous carcinoma.
DR. RESTAINO: I'm going to move to strike.
BY DR. RESTAINO:
Q. Is it -- the question, Doctor, is it reasonable for a reasonable scientist to agree with these scientists from the NCI?
MS. MILLER: Objection. Asked and answered. Vague. Many other things, but my head hurts

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too much to list to them all.
THE WITNESS: Which tissue? Which cell you said? Different scientist has a different --
BY DR. RESTAINO:
Q. Doctor, do you agree, then, that rapid cell division in the generic sense increases the possibility for replication error?
MS. MILLER: Objection.
THE WITNESS: I'm a scientist, okay. Our research is involving very similar in this field. And we are the experts on the endometrial repair and cancer genetics.
So I can tell you as one -- I am one of this authority in this replication and DNA damage repair.
This question is making no sense.
It depends on the context, tissue, cell lines, and methodology you used.

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This question, I cannot answer. Probably if you break up into 20 specific questions, maybe I can answer you individually.
BY DR. RESTAINO:
Q. Okay. Doctor, is limitless replication potential one of the hallmarks of carcinogenicity?
MS. MILLER: Objection.
THE WITNESS: So you are talking about the cancer, what is the feature of cancer? So you said endless replication --
MS. MILLER: Limitless.
BY DR. RESTAINO:
Q. Limitless.
A. Oh, limitless.
MS. MILLER: Like without limits.
THE WITNESS: Okay. Replication. Is like uncontrolled proliferation.
BY DR. RESTAINO:
Q. Is that one of the hallmarks

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of cancer?
MS. MILLER: Objection. Vague.
THE WITNESS: It's one of them is not sufficient for the cancer. But you said carcinogenicity, which is wrong. Carcinogenicity meaning initiation. So in the precursor lesion, which I'm the expert in the precursor of high grade serous carcinoma, which is p53 signature, and STIC. In the p53 signature, there is no proliferation at all.
BY DR. RESTAINO:
Q. Doctor, in what -- it is true, is it not, that another hallmark of cancer is self-sufficiency and growth signals, correct?
MS. MILLER: Objection.
THE WITNESS: In which context? And what kind of evidence that -- where does that

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statement come from?
BY DR. RESTAINO:
Q. You're not familiar with that statement? "Self-sufficiency and growth signals is a hallmark of cancer"?
A. Can you show me the reference?
Q. We'll get back to that in a moment.
A. Please.
Q. How about insensitivity to antigrowth signals? Is that a hallmark of cancer?
A. What?
MS. MILLER: Objection.
BY DR. RESTAINO:
Q. Insensitivity to antigrowth signals. Have you heard that phrase before?
MS. MILLER: Objection.
THE WITNESS: It depends on the cancer type. But in ovarian high grade carcinoma here, I don't see any evidence. If you have

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one, please show me.
BY DR. RESTAINO:
Q. Okay. How about tissue invasion and metastases, is that a hall -- are they a hallmark of cancer?
MS. MILLER: Objection.
THE WITNESS: It's one of the features.
BY DR. RESTAINO:
Q. Evading apoptosis, is that another feature or hallmark of cancer?
MS. MILLER: Objection.
THE WITNESS: It is -- okay. It's one of the features that someone proposed. But it depends on the tissue type. In ovarian cancer I did not show -- I did not see any cogent evidence to show that biological evidence that this occur in ovarian high-grade serous carcinoma. If it's HGSC, it's what we refer. But I would agree, this is in generic. But if you focus on a

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specific type, you need -- one need to be careful.
BY DR. RESTAINO:
Q. Let's look again at the Trabert paper, sir. The very next sentence states, "Ovarian cancer has been linked to several events and conditions which are related to inflammation and repair, including incessant ovulation, endometriosis, exposure to talc and asbestos, and in some studies, pelvic inflammatory disease [Reviewed in [2]]."
Did I read that correctly, sir?
A. It is stemming from the review articles.
Q. Okay. Do you agree with the statement, sir?
MS. MILLER: Objection.
THE WITNESS: I don't see any credible science and biological evidence to support this argument. And this, you show me the

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good references.
BY DR. RESTAINO:
Q. Do you agree that incessant ovulation has been linked to ovarian cancer?
A. It has been proposed.
Q. Do you agree that endometriosis has been epidemiologically linked with ovarian cancer?
MS. MILLER: Objection.
THE WITNESS: Endometriosis, there are different types. Only certain type can do that, can have -- increase very, very slight risk.
BY DR. RESTAINO:
Q. So you're saying there's a chance?
MS. MILLER: When you say -- I'm confused. If you understand his answer. When you say only certain types, are you talking about other than certain types of endometriosis, or only certain

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types of ovarian cancer?
THE WITNESS: Oh, I'm sorry. Look at this chart, okay. So this is the origin of different types of ovarian cancer. You can see there is -- fallopian tube epithelium is the origin of high grade and low grade serous carcinoma, we see here.
And endometriosis may be related to endometrioid and clear cell carcinoma. Actually, this is very good evidence.
BY DR. RESTAINO:
Q. So these --
MS. MILLER: Let him finish his answer.
THE WITNESS: How do you know what I'm going to say? I'm sorry. I want to give you the complete answer.
You see endometriosis, especially the endometrioid type, cancer and clear cells, they are

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related to ovarian endometriotic cysts, or so-called endometrioma, so-called chocolate cyst.
So that is where the origin of this clear cell endometrial carcinoma, form this endometrioid cyst. But the regular invasive endometriosis and the superficial endometriosis will not cause clear cell and malignant carcinoma. Why I know this? Because we just publish one paper on this issue.
DR. RESTAINO: I'm going to move to strike as unresponsive.
MS. MILLER: It was completely responsive. You asked him whether endometriosis was related to endometrioid --
THE WITNESS: Yeah. Right.
MS. MILLER -- whether endometriosis was related to ovarian cancer. And he's giving you a full answer, because there is no one entity called ovarian

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cancer. If he wants to talk about the subtypes, that's a totally, completely responsive answer.
THE WITNESS: Otherwise, I --
MS. MILLER: Otherwise your question was misleading.
BY DR. RESTAINO:
Q. Doctor, these researchers from the National Cancer Institute write that endometriosis is linked with ovarian cancer. Do you disagree or agree with that?
A. Can you say that one more time? Because now we are jumping endometriosis to this.
Q. The authors here state --
A. Yeah.
Q. -- "Ovarian cancer has been linked to several events and conditions which are related to inflammation and repair" --
A. Right.
Q. -- "including incessant

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ovulation."
A. Right.
Q. Endometriosis, do you agree that endometriosis has been linked to with inflammation and ovarian cancer?
MS. MILLER: Objection.
THE WITNESS: You said linked to the inflammation, that I don't know.
BY DR. RESTAINO:
Q. Okay. How about exposure to talc and asbestos?
A. Definitely not.
Q. You disagree with that. "And in some studies pelvic inflammatory disease."
Do you agree with that?
MS. MILLER: Objection.
THE WITNESS: I did not say I agree.
MS. MILLER: With what?
THE WITNESS: With what -- and what -- what's your subjects?
BY DR. RESTAINO:

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Q. Do you need me to read the sentence to you again?
A. No. No.
Q. Because I will. I'll read it for as long as it takes the Number 1 pathologist in ovarian cancer to get it.
Ovarian cancer -- you understand that, right?
MS. SHARKO: Wait, wait, wait, Doctor.
MS. MILLER: Let's take a break so you can relax. Let's take a break so you can catch your breath because you are kind of shouting at the witness.
THE WITNESS: Right. Right.
MS. MILLER: Let's go off the record.
THE VIDEOGRAPHER: Okay. Go off?
I need confirmation from both sides.
DR. RESTAINO: Yes.
THE VIDEOGRAPHER: The time

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is 3:11 p.m. We are going off the record.
(Short break.)
THE VIDEOGRAPHER: The time is 3:21 p.m. We are back on the record.
BY DR. RESTAINO:
Q. Welcome back, Doctor.
Now, Doctor, several times today if I recall correctly, you've stated that you are -- your publications are frequently cited in the medical literature; is that correct?
A. Frequently means -- do you have a quantification?
Q. I -- I think you said, was it 30,000 times?
A. 32,800. I don't know. I cannot keep track on that.
Q. Okay. But it's about 30,000 or 32,000?
A. About.
Q. And that means that there is a lot of publications that are -- that

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are relying upon your publications, correct?
A. Rely on. I would say they may reference my paper --
Q. Okay.
A. -- as part of their purpose for that specific study. But I cannot know how they cite it. Because there's 33,000. I cannot track on that.
Q. Okay. Okay that's a big number, isn't it?
MS. MILLER: Objection.
THE WITNESS: Some number.
BY DR. RESTAINO:
Q. Okay. I believe we now marked as Shih Exhibit 15, a paper by Douglas Hanahan and Robert A. Weinberg titled "The hallmarks of cancer" published in Cell in January of 2000.
(Document marked for identification as Exhibit Shih-15.)
BY DR. RESTAINO:
Q. Doctor, are you familiar

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with this paper?
A. I want to make sure. Cell, January 7th, 2000. That's 19 years ago.
Q. Correct.
A. "The hallmarks of cancer," by Hanahan and Robert A. Weinberg. I remember, saw this paper before.
Q. Okay. In fact I will represent to you that last night when I checked on this paper, this one paper has been cited 30,119 times all by itself.
Have you cited this paper in your publications?
A. I cannot remember. I'm on my 300 something papers --
Q. Okay.
A. -- whether I cite this or not.
Q. Okay. If you would turn to Page 2, they have a diagram.
A. You mean Figure 1, acquired capabilities of cancer?
Q. Yes, sir. And they describe these as the six hallmarks of cancer, do

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they not?
A. That's the legend in the figure.
Q. Okay. And one of them is self-sufficiency in growth signals. Agreed?
A. You mean the green, the top one, yes.
Q. Yes. And then evading apoptosis is one of the hallmarks of cancer, correct?
A. Yes.
Q. And then -- and alongside of that is insensitivity to antigrowth signals, correct?
A. Correct.
Q. And then down below they have three, the one on the left is sustained angiogenesis. Agreed?
A. Yes.
Q. And then tissue invasion in metastases, correct?
A. I saw that.
Q. And then limitless --

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A. Replicative.
Q. -- potential, correct?
A. That's in the figure.
Q. That's all in the figure in the paper that's been cited 32,000 times.
Now, do you know if these authors have published a follow-up to that 2000 paper?
A. I did not follow this paper.
Q. Okay.
(Document marked for identification as Exhibit Shih-16.)
BY DR. RESTAINO:
Q. We have marked as Shih-16, Hanahan and Weinberg, 2011, "Hallmarks of cancer: The next generation."
Do you recall seeing this?
A. I cannot recall.
Q. Okay. This is published in the journal Cell. You've published in the journal Cell yourself, have you not?
A. I am co-author in Cell.
Q. Okay. And I will represent

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to you that as of yesterday, this paper by itself has been cited 34,292 times. So with the first paper, these two papers have been cited over 60,000 times.
Now, we don't know, do we, of those articles that have referenced this how many times those references have been referenced, would you agree?
A. How many references have been referenced, what does that mean?
Q. Well, if these two papers --
A. Yeah.
Q. -- have been cited over 60,000 times, then those 60,000 papers may have also been referenced, correct?
MS. MILLER: Objection. That is not logical.
THE WITNESS: They are not related to these two papers. They are just --
BY DR. RESTAINO:
Q. Fair enough. I'll -- I'll --
A. How can this be --

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MS. MILLER: When you say they were cited 60,000 times, do you mean 60,000 times in 60,000 separate papers or were they sometimes cited in the same paper? I just don't -- I think there's some illogic in the math there but --

DR. RESTAINO: How can they be cited in the same paper?

MS. MILLER: Okay. You could cite both of these.

DR. RESTAINO: No -- okay -- or both papers --

MS. MILLER: If this was cited 30,000 times and this was cited 30,000 times. In diagrams, some of them may have been cited in the same paper.

DR. RESTAINO: Well, as it happens in PubMed, when papers are cited, they're cited individually. The first one was cited over 30,000 times. The second one has

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been cited over 30,000 times. Collectively, these two papers --

MS. MILLER: You said then those 60,000 papers. I don't think you established they've been cited in 60,000 papers.

THE WITNESS: It should be 60,000 citations. Not papers.

BY DR. RESTAINO:

Q. Okay. Now, let's move on to, on this paper here, to Page 658. Okay. And they have --

A. Hold on.

Q. 658 and Figure 3.

A. So you are referring Figure 3?

Q. Yes, sir.

A. Imaging hallmarks and enabling characteristics.

Q. All right. Now, in addition to the six hallmarks of cancer that they published in 2000, they've now added deregulating cellular energetics and avoiding immune destruction as emerging

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hallmarks, have they not?

A. I saw those boxes.

Q. And then down below they have enabling characteristics on the left, "Genome instability and mutation," and on the right, "Tumor promoting inflammation," correct?

A. Okay. Okay. I need to understand this diagram, okay. So this emerging hallmarks and enabling characteristics. I cannot understand the individual symbols, can you? This, this, this, this.

Q. Without getting into what the two individual signals are, just directing your attention to the new ones that they've added. And if you look over on Figure 3 on the legend on the right-hand side, do you see the verbiage --

A. I need to read. I'm sorry.

Q. If you look at the bottom of the legend.

A. So additional hallmarks of

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cancer are involved in the pathogenesis of some and perhaps...

(Reading to himself.)

Because neither capability is yet generalized and fully validated. Neither.

Thank you for your patience.

Q. Doctor, the final sentence in that legend they write, "Inflammation by innate immune cells, designed to fight infections and heal wounds, can instead result in their inadvertent support of multiple hallmark capabilities, thereby manifesting the now widely accepted" -- "widely appreciated tumor-promoting consequences of inflammatory responses."

Did I read that correctly?

A. This is talking about cancer in general.

Q. Doctor, did I read that correctly?

A. You read correctly as shown in the figure legend.

Q. Okay. Now, do you have any

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objective evidence to contradict Hanahan and Weinberg in this paper that's been cited over 32,000 times that inflammation by innate immune cells designed to fight infections and heal wounds can instead result in their inadvertent support of multiple hallmark capabilities, thereby manifesting the now widely accepted tumor-promoting consequences of inflammatory responses?

Do you disagree with that statement?

MS. MILLER: Objection.

THE WITNESS: It depends. If we talk about specific type of cancer like ovarian high grade serous carcinoma, I don't see evidence, cogent evidence and credible science to do that.

I think Dr. Weinberg is saying in general, okay, take every cancer, testicular cancer, prostate cancer, brain tumor, everything together into

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consideration.

But it did not specify ovarian cancer can do that. If you have evidence that Dr. Weinberg say ovarian cancer, could you please show me?

BY DR. RESTAINO:

Q. Okay. So is it your opinion that in discussing the hallmarks of cancer, each and every cancer has to be looked at individually?

A. That's --

MS. MILLER: Objection.

THE WITNESS: That's a totally different question. Okay. You ask me another set of question.

BY DR. RESTAINO:

Q. I did. It was another question.

A. Okay. So could you repeat your new question one more time.

Q. Yes. Is it your opinion that when discussing the hallmarks of

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cancer as these two gentlemen did in these two separate publications that have been cited over 60,000 times, that you have to look at each and every cancer specifically? Is that your expert opinion?

A. So we are, as a scientist, I will tell you what we're going to do. We want to demonstrate the credible science and the cogent evidence of biological plausibility, may include those hallmarks they say, but we did not find any plausible evidence at this moment.

I think this is very good guideline for the general cancer biologist. But for individual one, we need to demonstrate at least some of these features.

So I did not say that I disagree with Dr. Weinberg as a whole in cancer biology in general, like teaching medical students.

What I'm saying, this -- we are still fighting. We try to struggle

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very much in our laboratory to find those evidence. So that's our aim. We want to find this evidence. But we don't have any evidence to show in ovarian cancer research.

Also, I want to tell you, Nobel Prize Laureate, the finding -- has been cited so many times.

So, again, I'm looking at the science, not where it come from, the institution, authors, and citations. Citation's a good indicator, but it does not mean too much. Especially as a review paper.

Q. You yourself have reported that you've been referenced over 30,000 times twice today, correct, Doctor?

A. Yes, I just tell you. That's a number that I tell you. But I cannot tell you that my reputation is solely based on my citation. It's based on my research findings.

Q. You state, "We try to struggle very much in our laboratory to

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find those evidence, so that's our aim. We want to find this evidence. We don't have any evidence to show in ovarian cancer research."

Do you have any evidence to show that the hallmarks and emerging characteristics as listed by Hanahan and Weinberg do not apply to ovarian cancer?

MS. MILLER: Objection.

THE WITNESS: I need to review your question. Okay?

What I said, there's no evidence to support that ovarian high grade serous carcinoma if this is the type we are talking about, because otherwise it's so confusing, because every type is different. That's the problem with epidemiologic studies.

So we'll go back.

So what you said is do not apply to ovarian cancer. What does that mean?

I said we don't have

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evidence to show, including, okay, this hallmarks in ovarian cancer precursor lesions, the high grade precursor means STIC and p53 signature. We don't have any evidence to show. It doesn't mean no evidence. It doesn't mean it's not applicable. Okay. We just don't have evidence to show. There's no credible science.

BY DR. RESTAINO:

Q. You don't have evidence to contradict these two researchers, correct?

MS. MILLER: Objection.

THE WITNESS: These two researchers, they claim -- they come up with these features in cancer biology in general. It cannot be applicable to specific cancer type, like, for example, cholangiocarcinoma, sarcoma, high grade serous carcinoma, low grade serous carcinoma, clear cell

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carcinoma, renal cell carcinoma, endometrioid carcinoma.

I don't find any cogent evidence for this biological mechanism in the literature.

DR. RESTAINO: I'm going to move to strike as nonresponsive.

BY DR. RESTAINO:

Q. Doctor, in the form of ovarian cancer that you study, any form, you can pick the form, whatever form you study, one hallmark of ovarian cancer is that it sustains proliferative signaling and keeps going, correct? That's a hallmark of every cancer known to man, correct?

MS. MILLER: Objection.

THE WITNESS: Can you say that one more time? Every single tumor cells?

BY DR. RESTAINO:

Q. Every single tumor --

A. Tumor. Not tumor cells, okay.

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Q. -- undergoes sustained proliferative signaling. That's what makes it an out-of-control cancer, correct? Every cancer.

MS. MILLER: Objection.

THE WITNESS: Not in their precursor lesion. That would be another different landscape. You talk about cancer including precursor in situ cancer, or are you -- you mean the metastases? If you say metastases, of course, they can expand, uncontrolled proliferation.

BY DR. RESTAINO:

Q. I'm talking about --

A. When you talk about cancer precursor, that's a different thing.

And this is our focus today, is whether talc and -- or asbestos can cause ovarian cancer. We should focus on the precursor lesion, not the big blown -- the full-blown, the cancer that kill patients.

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Q. Okay. I know that's what you want to focus on, but there are many other experts that are not focused on that and they're looking at the totality of the evidence of linking ovarian cancer with inflammation and inflammation secondary to talc.

And inflammation-promoting properties has been listed by these authors as widely appreciated in the medical field, correct?

A. Could you show me the -- the references -- references to show this part?

Q. I've showed you the article.

A. That's a review.

Q. Okay.

A. But do you have any single paper that you claim that you were happen in ovarian cancer?

Q. Do you have a single paper that shows that inflammation is not pro-growth in the cancer arena?

MS. MILLER: Objection.

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BY DR. RESTAINO:

Q. A single paper that shows that -- that inflammation, whether it's caused by the cancer itself or the body's innate response to that cancer, a single paper that shows that inflammation does not promote the growth of the cancer?

MS. MILLER: Objection.

Please let me get my objection. I know you're excited to answer.

But that was objectionable.

THE WITNESS: Yeah, right.

BY DR. RESTAINO:

Q. Okay. What don't I strike -- do you need the question asked again, Doctor?

A. Please.

Q. Okay. Doctor, can you show us or refer us to a single paper that is of cogent evidence which shows that inflammation, whether caused by the tumor or promoting the tumor does not affect the growth of cancer?

MS. MILLER: Objection.

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MR. LOCKE: Objection.

THE WITNESS: I think I answered your question in this morning's discussion, I believe. What I said is scientists -- okay. I will say science is evidence -- evidence-driven, evidence-driven.

We can prove positivity to show the evidence, but we cannot prove negativity, because this against the science practice. This is not logic in science. How can we prove there is no -- no tumor in a person? We need to see the tumor, so we can say, oh, you are a cancer patient, until we find it.

DR. RESTAINO: I'm going to move to strike.

BY DR. RESTAINO:

Q. Doctor, what paper, peer-reviewed, published, are you relying upon for the basis of your opinion that inflammation plays no role in the growth

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promotion of ovarian cancer?

MS. MILLER: Objection. He's answered this question multiple times, and it was an objectionable question even before he answered it multiple times.

MS. PARFITT: "Objection" is fine.

THE WITNESS: I answer your questions multiple times, and my answer was remains the same if you keep asking me 100 times.

BY DR. RESTAINO:

Q. I'm sorry. I -- I missed your -- the name of the paper that you -- that you are relying upon. I'm -- I'm sharing with you a paper that has been cited over 32,000 times which states that it is now widely appreciated tumor-promoting consequences of inflammatory response.

Your response was that it doesn't apply to ovarian cancer. I'm asking for one paper --

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MR. LOCKE: Objection.
BY DR. RESTAINO:
Q. -- that is cogent evidence that the tumor-promoting consequences of inflammatory response does not apply to ovarian cancer.
MS. MILLER: Objection. Same -- I'll --
THE WITNESS: Same answer. I can repeat one more time.
BY DR. RESTAINO:
Q. Give me the name of the paper.
A. I can give you one more time my answer.
Q. I want the name of the paper.
A. Science -- science, practicing science, as a scientist, our job is to find the positive evidence to support hypothesis. This by no means we can come up with negative results because this is not logic in science.
Q. You can't come out with

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negative results --
A. Because this a logic problem. Okay. We cannot prove negativity. The science is -- is evidence driven.
Q. Okay.
A. Only evidence there can become positive. Okay. With a positive, you can claim something to be further tested. But no one in the whole wide world can prove negativity. Period.
Q. Okay. So you can't give me the name of a single paper?
A. The answer is I just --
MS. MILLER: Objection. Doctor, please let me object.
BY DR. RESTAINO:
Q. Okay. And -- and, Doctor, it is your expert opinion that it is your job to come up with positive evidence to support a hypothesis, and by no means you can come up with negative results, because that's not logic in science, correct?

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MS. SHARKO: Object to the form.
THE WITNESS: No, what I said is that's the scientist's job. Okay. If you have a hypothesis, talcum powder can cause ovarian cancer, you need to show the cogent evidence and credible science to support the biological plausibility. That's what I said. It doesn't mean I -- okay, I need to review those evidence --
BY DR. RESTAINO:
Q. Okay. And --
A. -- to see whether they are credible or not.
Q. And have you reviewed evidence that shows that inflammation does not promote ovarian cancer?
MS. MILLER: Objection. Asked and answered like 15 times.
THE WITNESS: I already answered.

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BY DR. RESTAINO:
Q. And you gave me the name of the -- okay, then, what is the -- what is the lead author's name of the paper that you were relying upon?
MS. MILLER: Objection. That's argumentive. That's misstating the witness's testimony. And he's answered this question in a hundred different forms multiple, multiple times.
BY DR. RESTAINO:
Q. Doctor, you can't name a single paper, can you?
MS. MILLER: Objection.
THE WITNESS: What kind of paper you are referring to?
BY DR. RESTAINO:
Q. A peer-reviewed published paper that contradicts Hanahan and Weinberg's paper, which has been cited 32,000 times, which talks about the widely appreciated tumor-promoting properties of inflammation.

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MS. MILLER: Objection.
BY DR. RESTAINO:
Q. Doctor, are you thinking, or --
MS. SHARKO: Well, you all were talking.
MS. MILLER: I don't even know where we are. I think --
MS. SHARKO: Same question.
MS. MILLER: Okay. Same question, same objection. It's been asked and answered in many, many different ways.
MS. PARFITT: The doctor needs to answer the question.
MS. MILLER: The doctor has answered the question.
MS. PARFITT: The doctor has not answered the question. The doctor --
THE WITNESS: I believe I answered the question.
BY DR. RESTAINO:
Q. You've given -- you've given

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me the name of the article you're relying upon?
A. I said -- I answered --
MS. MILLER: That is a misleading question.
MS. PARFITT: Objection to form, Counsel, is really the -- the appropriate response. We tried to be patient with that.
MS. MILLER: Well, I'm trying to be patient --
MS. SHARKO: Well, you guys also can't just make editorial comments on his answer.
MS. PARFITT: I don't think that we have.
DR. RESTAINO: The record will report what the record reports.
MS. MILLER: You have the answer multiple times.
BY DR. RESTAINO:
Q. Have you ever published a paper that contradicts the statement that

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the tumor-promoting properties of inflammation is widely appreciated?
MS. MILLER: Objection.
THE WITNESS: In my research team, we have many top priority projects. And this is not the research area we want to be engaged. We want to develop early detection methods and effective treatments for ovarian cancer patients.
BY DR. RESTAINO:
Q. Is that no?
MS. MILLER: Objection.
THE WITNESS: What has been no?
BY DR. RESTAINO:
Q. Is your answer no, that you've not published a paper that refutes Hanahan and Weinberg's statement that the tumor-promoting properties of inflammation are widely appreciated?
MS. MILLER: Objection.
THE WITNESS: I answered

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your question before.
THE VIDEOGRAPHER: Counsel, we need to go off the record. The time is 3:50 p.m. We are going off the record.
(Short break.)
THE VIDEOGRAPHER: The time is 3:56 p.m. We are back on the record.
DR. RESTAINO: I'm going to ask Madam Court Reporter, Michelle, to mark the deposition regarding the discussion we had regarding an article refuting the Hanahan and Weinberg analysis.
BY DR. RESTAINO:
Q. And, Doctor, I want to change channels, so to speak. And let's go to your expert report. And if you would look on Page 5, and there you have a criticism of the cancer cell lines that Dr. Saed has used, correct?
A. That's my opinion.
Q. Okay. Down at the bottom of

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it -- one, two, three, four -- five lines up you state, "Another problem with the study design is the researchers mistakenly used an A2780 cell line as an ovarian high grade serous cancer cell line. But in fact A2780 is unlikely an ovarian high-grade serous cancer line and should not have been relevant in this study, reflecting the limited knowledge of the research group in studying ovarian cancer (Anglesio, et al., 2013; Domcke" -- D-O-M-C-K-E -- "et al., 2013.)"

Did I read that correctly, Doctor?

A. That is what is my opinion.

Q. Now, was your opinion there derived from reviewing the Saed paper itself?

A. You mean this publication's precursor?

Q. That publication? It's --

A. No, its precursor, meaning the manuscript.

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Q. Okay. And you looked at that, correct?

And let's look at the study --

MS. MILLER: Wait a minute. This is under a part of his report that says Dr. Saed's statements in his expert report, not the part of the report that says Dr. Saed's in-press paper. There are two sections of this report. One refers -- I just want to make sure that the record is clear because I think that was not accurate.

Dr. Saed's statement in his expert report, that's where he discusses that.

Then on Page 6 it says Dr. Saed's in-press paper. So this is based on the expert report, based on looking at the report. That's what it says.

DR. RESTAINO: What is based on the expert report?

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MS. MILLER: If you look at Dr. Shih's expert report, I think what you said misstates what is here. He has two sections in his expert report as I'm reading it now.

One says Dr. Saed's statement in his expert report. Another says Dr. Saed's in-press paper in Reproductive Science. So are you focused on the expert report or Reproductive Science manuscript now?

DR. RESTAINO: I'm focused on Dr. Shih's expert report on Page 5.

MS. MILLER: Right.

DR. RESTAINO: Where he has a paragraph there titled "Use of cancer cell lines."

MS. MILLER: Right. And that refers to Dr. Saed's expert report, not Dr. Saed's manuscript. So you misstated that. I just

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wanted to get that clear on the record.

DR. RESTAINO: Okay. Duly noted.

BY DR. RESTAINO:

Q. Okay. I would like to take a look at Dr. Saed's published paper?

A. This one. In Reproductive Science, 2019?

Q. Correct. If you would turn, Doctor, to the second page on the lower left-hand side there's a section titled "Material and Methods." And then "Cell Lines."

Do you see that, sir?

A. Right. I saw it here.

Q. Okay. And there they discuss, under their cells and the cell lines, that they use ovarian cancer cells capital S -- all caps -- SK-OV-3(ATCC), A2780 (Sigma-Aldrich at St. Louis, Missouri), and TOV112D (a kind gift from Gen Sheng" -- S-H-E-N-G -- "Wu" -- W-U -- "at Wayne State University, Detroit,

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Michigan), and normal cells, human macrophages (EL-1; ATC, Manassas, Virginia), human primary normal ovarian epithelial cells (Cell Biologic Chicago, Illinois), human ovarian epithelial cells (HOSEpiC; ScienCel" -- S-C-I-E-N-C-E-L -- "Research Laboratories Incorporated, Carlsbad, California), and immortalized human fallopian tubes secretory epithelial cells (FT33; Applied Biological Materials, Richmond, British Columbia, Canada) were used."

Did I read that correctly, Doctor, with all those letters and everything?

A. This were -- this sentence has been written in this paper.

Q. Okay. They use normal cell macrophages in their study, did they not?

MS. MILLER: Objection.

BY DR. RESTAINO:

Q. That's the fourth line?

A. I don't think they're normal anymore. If it become a cell line,

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meaning they're immortalized, and the macrophages, as you know, according to Dr. Weinberg, the charts, they are normal, but the cell line, they can be maintained in tissue culture, and they can divide all the time.

So this is -- by no means is normal macrophages. It has some -- as Dr. Weinberg said, just as you, candidly, as you do to me, that's one of the feature of cancer.

Q. But in normal cells, like in normal macrophages, they have a limited number of mitotic events before they begin to die out, correct?

A. I don't even know whether human macrophages can ever replicate in tissue culture, because they are terminally differentiated immune cells.

Q. Okay. Well, in addition to using the macrophages as listed in the paper, they also used human primary normal ovarian epithelial cells, correct?

A. You mean the human primary

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normal epithelial -- Cell Biologicals, Chicago, Illinois.

I never know this so-called normal ovarian epithelial cells, because every time, when they culture the epithelial cells, they have really finite life spans. They cannot -- they are not cancer, right? So as we remember vividly from the Weinberg's charts, this normal cells cannot proliferate all the time.

But in order for that society to study in culture, they need to expand that. And when they expand, they are not normal epithelial cell already. When we look at normal epithelial cells in human tissue, they may not be proliferative. So I don't think how relevant this cell line will be to this study.

Q. Have you ever used the human primary normal ovarian epithelial cells from Cell Biologics, Chicago, Illinois?

A. I cannot recall. But if I did, we are doing -- we are asking

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different scientific questions, okay. It's totally irrelevant.

Q. Okay. In addition for his study, they used human ovarian epithelial cells or HOSEpiC obtained from ScienCel Research Laboratories, correct?

A. Yeah, they're in California. This has been written.

Q. Okay. And as I'm going through this, the only cell line that you're criticizing in your expert report is that they use the A2780, correct?

A. Let me go back to my report.

Q. Yes, sir. It's Page 5, paragraph titled "Use of Cancer Cell Lines."

MS. MILLER: Are you asking anywhere in his report if that's the only place --

THE WITNESS: I saw this paragraph.

At the time I believe this is the most important deficiency in the methodology, meaning cell

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lines cannot -- ovarian cancer cell lines cannot be used to answer the question of where it starts. You need to start from the normal epithelial cells. So this is -- I -- this is totally methodology incorrect.

BY DR. RESTAINO:

Q. Okay. And Dr. -- the Saed team also utilized immortalized human fallopian secretory epithelial cells, FT33, obtained from Applied Biological Materials, correct?

A. It has been written. But that's a really bad idea.

Q. Okay. Whether it's your opinion of a good idea or a bad idea, did -- do you discuss in your expert report the fact that they use these -- these various cell lines?

A. To the scientific community, I think this is so obvious flaw. So I just mention the ovarian cancer cell line issue here. But I think everybody will

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agree, this is totally not correct methodology to answer the specific question about the carcinogenesis.

Q. The Saed team tested three cancer cell lines in addition to normal cell lines and immortalized cell lines, did they not?

A. I will not say normal cell line. A cell line cannot be normal anymore.

Q. They used ovarian cancer cells, SK-OV-3, correct?

A. Yes.

Q. That's not listed in your expert report, is it?

MS. MILLER: That's a lie. It's right here on Page 6. I'm looking at it.

DR. RESTAINO: Well, it's not a lie. I just -- I just word-searched it.

MS. MILLER: Just -- okay. SK-OV-3? I'm looking at it.

DR. RESTAINO: It's got no

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hyphen in it.

MS. MILLER: Oh, it's got no hyphen.

THE WITNESS: It's the same, everybody know SK-OV-3.

MS. MILLER: I'm sorry. That was -- object to foundation. I retract what I said. I just was looking right at the word.

BY DR. RESTAINO:

Q. Okay. Doctor.

A. Yes.

Q. Now, talking about the A2780 cell line. In fact, despite your criticism, the medical literature is replete with research articles pertaining to ovarian cancer which utilize A2780, correct?

A. Could you repeat the question one more time, slowly.

Q. Yes. The medical literature is filled with current research articles pertaining to ovarian cancer and utilizing the A2780 cell line?

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MR. LOCKE: Objection.

THE WITNESS: This cell line has been used in the past without knowing that the origin is now ovarian cancer.

And as a result, as you can see, the -- the reference I cited, Domcke 2013 and Anglesio 2013. I think that's why this is so important. I think these are two papers can allow, as a scientist, we try very hard to do ovarian cancer research, that we need to be really careful about our cell lines and the most up-to-date knowledge we should perform in tissue culture studies.

BY DR. RESTAINO:

Q. Doctor, would you be surprised if I represent to you that since January 1st of 2018, so we're dealing with maybe 15 months, not going back to Domcke in 2013. Since January 1st, 2018, 139 peer-reviewed

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articles have been published utilizing the A2780 ovarian cancer cell line?
MR. LOCKE: Objection.
BY DR. RESTAINO:
Q. Would that surprise you, sir?
MS. MILLER: Objection.
THE WITNESS: That's unfortunate that scientists did not be aware of that. Some scientists may be aware of that, but they still use A2780.
You know why? Because this cell line is very easy to grow and people love it, because it's -- it proliferates very well. So people know maybe, they know that this is not a good model. But they still continue using it, pretending nobody know this trick.
BY DR. RESTAINO:
Q. So it is your subjective opinion that the A2780 is not an adequate cell line to use, but objectively

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researchers continue to publish the results including for treatment of ovarian cancer; isn't that correct?
MS. MILLER: Objection.
MR. LOCKE: Objection.
BY DR. RESTAINO:
Q. I'll represent to you, Doctor, functional and transcriptomic characterization of carboplatin resistant A2780 ovarian cancer cell line was published in biological research last week. And these researchers are looking at this A2780 ovarian cancer cell line that they've now made carboplatin resistant in order to determine what they can do to help patients who become resistant to carboplatin therapy. Are you aware of that, Doctor?
MS. MILLER: Objection.
THE WITNESS: I need to see the reference. Do you have the paper with you?
BY DR. RESTAINO:
Q. I'm just asking you if you

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are aware of that publication as of last week?
MS. MILLER: Objection.
THE WITNESS: In order -- in order to answer your question, I need to see that.
BY DR. RESTAINO:
Q. Is carboplatin the most used, widely used chemotherapy regimen for ovarian cancer?
A. I don't really --
MS. MILLER: Objection.
THE WITNESS: This is totally irrelevant. We are talking about the carcinogenesis.
Ovarian cancer precursor, talcum powder, including Johnson & Johnson product, can cause ovarian cancer, then we are talking about the technical part of cell lines.
I think we are off track.
BY DR. RESTAINO:
Q. Then would you withdraw your criticism of Dr. Saed's use of A2780?

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MS. MILLER: Objection.
THE WITNESS: No. It's wrong --
BY DR. RESTAINO:
Q. Then it is -- then it is irrelevant to our discussion. I know you want to talk about your work. But we're also here to talk about the flaws you feel that Dr. Saed has in his paper?
A. Okay.
Q. And my representation -- representation to you is that despite your subjective opinion, A2780 is still being widely used and published up to last week.
MS. MILLER: Objection.
MS. SHARKO: That's not a question.
MS. MILLER: Please give me time me object.
That's true too.
THE WITNESS: What do you mean widely used?
BY DR. RESTAINO:

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Q. How about 139 publications.
A. As compared to what?
Q. As compared to zero publications?
A. Where does zero come from?
Q. Well, if it was no longer a recognized viable cell line, then people would stop using it and publishing it. Peer reviewers wouldn't approve it, and journals wouldn't publish it; isn't that true?
MS. MILLER: Objection.
MR. LOCKE: Objection.
MS. MILLER: We are synchronized.
THE WITNESS: That's why good science is so important; otherwise, how can we cure ovarian cancer now, right? It's because we need to really update and keep abreast of new knowledge, and using the correct methodologies. So I only care about the science, whether the credible science,

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cogent evidence can support biological plausibility regarding this issue. That's my concern. And this is incorrect cell lines to be used. Totally incorrect and not relevant to ovarian cancer.
BY DR. RESTAINO:
Q. Have you conducted research of PubMed to look at how many individuals are still publishing using A2780 since January 1st of 2018?
MS. MILLER: Objection.
THE WITNESS: I have so many thing to do. Top priority. This is incorrect methodology to be used, why it bother me.
BY DR. RESTAINO:
Q. Okay. I'll move on. Let's take a look at your expert report where you talk about the irrelevance of CA-125.
A. Which page? I'm sorry.
Q. I believe it's on Page 5?
MS. MILLER: So again, I just want to point out that it's a

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little bit confusing, because, as I noted -- and I think this is why you didn't find the SKOV thing. But this -- there's a section on Dr. Saed's statements in his expert report as one, and then Dr. Saed's in-press paper, and so CA-125 is covered both on Pages 5 and 7. And that was also what happened with the cell lines, why you didn't find it.
So just specify whether you're referring to the CA-125 discussion on Page 5 or Page 7.
DR. RESTAINO: Okay. I'm looking --
MS. MILLER: That was some confusion in the last round of questions.
DR. RESTAINO: I appreciate that. Thank you. Yes.
BY DR. RESTAINO:
Q. I'm looking at your paragraph on Page 5 wherein you -- it's

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titled "Irrelevance of CA-125."
Do you see that, sir?
A. Yes.
DR. RESTAINO: Jessica, are you on the same page?
MS. MILLER: Yep.
BY DR. RESTAINO:
Q. Okay. Now, CA-125 stands for cancer antigen 125, correct?
A. Correct.
Q. And an antigen is a toxin or a foreign substance for which the immune -- the body has an immune response, including the production of antibodies, correct?
A. No.
Q. Well, how -- okay. Then I'll use your definition. How do you define an antigen?
A. It's not my definition. It's a scientific definition. It's not only me. It's everybody accept.
Q. Sir, I'll use your definition or the definition that you

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have adopted from the scientific community. What is an antigen?
A. Antigen is the protein that can be recognized by our immune system.
Q. CA-125 is expressed as a membrane-bound protein on the surface of cells that undergo metaplastic differentiation into mullerian epithelium, correct?
MS. MILLER: Objection. Are you reading from something?
DR. RESTAINO: My notes.
THE WITNESS: What do you mean "under surface of cells"? I can't understand.
BY DR. RESTAINO:
Q. Oh, the protein on the surface of the cell.
A. Oh, on the cell. Not under.
Q. Right. Doctor, I'll adopt your definition of an antigen, but that's what CA-125 --
A. Well, I'm not finished.
MS. MILLER: Are you

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withdrawing that question? Or do you want him to answer that question? I just -- again --
THE WITNESS: I'm not finished reading your thoughts.
BY DR. RESTAINO:
Q. Okay.
A. CA-125 is also known as a mucin 16, was first identified by Dr. Bob Bast at M.D. Anderson Cancer Center.
So, I am not sure this is correct. You said, metaplastic differentiation and into mullerian epithelial cells. I don't know that's correct, unless you show me the reference.
Q. Do you know it to be incorrect?
A. I need to see the reference to make sure you are correct.
Q. Okay. I'll -- you then in your paragraph that we're reading from, irrelevance of CA-125 finding, you talk about cancer specific -- or cancer

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biomarker, correct?
A. You refer to the Line 3, is definitely not a cancer-specific biomarker. Is that one?
Q. The word "biomarker" is used several times. I'm just going to ask you what you mean by biomarker?
A. Oh. Okay.
MS. MILLER: Objection.
THE WITNESS: Biomarker -- biomarker is a term generally used in different research and by different meanings for different scientists and medical doctors. By the CA-125, is biomarkers, meaning it is something associated with ovarian cancer but not a precursor. That's the point. Not a precursor, but ovarian cancer.
So what happened is CA-125 -- usually I call it MUC16, same thing -- is expressed by the mullerian, normal mullerian duct epithelial cells.

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So every woman has a low level of that. But ovarian cancer, when they become transformed -- are you ready?
If they are transformed, they have more and more cells. It may not be that individual tumor cells express higher, but because the number is more.
So this is very different. They are not causal. They are just biomarkers. There are so many biomarkers without known etiology or biological mechanism.
In terms of tumor progression -- I mean in terms of tumor initiation.
So it has been shown, CA-125 in a serum can be a marker to follow, monitor, disease progression, but never be used as biomarker to identify ovarian cancer in the detection and screening.

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And it is by no means is it important in the transition of normal fallopian tube to a STIC or p53 signature.

So FDA approved, this can be followed, monitored to see if we have a cancer. I think this is important because that's --

DR. RESTAINO: Doctor, I'm going to move to strike.

BY DR. RESTAINO:

Q. I just asked you what's your definition of a biomarker. If I asked you the time, I don't need for you to make a watch. I just want to know the time.

What is a biomarker?

A. Biomarker is different types, tissue bio marker, serum biomarkers. Do you want me to continue or not?

Q. I just want you to define a biomarker so we get to the --

A. That's why I'm going to

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define. Biomarkers, like serum biomarkers, CA-125, has been approved by FDA to -- as a biomarker -- this is so irrelevant -- to monitor whether the tumor come back.

Q. Doctor, I understand that you want to get to that.

A. That's biomarkers, right?

Q. Doctor, would you agree that a biomarker is a measurable substance in an organism whose presence is indicative of some phenomenon, such as disease, infection or environmental exposure? That's a biomarker. Would you agree with that?

A. I need to see your -- what you said. I think this is one of the definitions.

Q. Okay. Is it an acceptable one to use for our purposes -- our discussion right now. Are you comfortable with using that?

A. I have only problem indicative. What do you -- what do you

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mean indicative?

Q. Suggesting.

A. It's -- it's causally related or not?

Q. No, just suggesting something is going on.

A. So it's no causally related as this biomarker.

Q. Okay. Now, if we look at your -- the paragraph you wrote, and once again, so the record is clear, we're looking on Page 5 of your expert report, in that paragraph, irrelevance of CA-125, you don't have a single reference for any of your opinions in that paragraph, do you?

A. Which paragraph, the top paragraph?

Q. Irrelevance of CA-125.

A. This is general medical knowledge. Every medical student will know.

Q. Okay. Doctor --

A. Every pathologist will know.

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Every medical doctor will know.

Q. Okay.

A. It's common, common knowledge.

Q. Does that mean that no, there's not a reference to the medical literature in that paragraph?

A. This -- there should be many. But this is a common sentence. So I don't need to reference each one.

Q. Okay. So it is your -- it is your opinion that CA-125 should not be considered as indicating the onset or heightened risk of the development of ovarian cancer, correct?

A. Definitely is not.

Q. Okay. I'd like to show you a paper we've marked as Exhibit 20 from the Journal of Ovarian Research.

(Document marked for identification as Exhibit Shih-20.)

THE WITNESS: Okay. Hold on one moment.

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BY DR. RESTAINO:
Q. And this one was published -- we're going back. This one was published ten years ago.
A. What.
Q. Okay. Now, if you look at the second page.
A. Okay.
Q. There's a heading there of CA-125 and ovarian cancer.
A. CA-125. Yes, I saw that.
Q. And do they state there, "The most widely used tumor marker in ovarian cancer, often considered the gold standard is CA-125, Reference 19"?
A. Let me see the 19.
19 is, okay, cancer antigen 125. That's 2008, 11 years ago.
Q. Yes. Do you agree that at that time, CA-125 was the most widely used tumor marker in ovarian cancer?
MS. MILLER: Objection.
THE WITNESS: What do you mean widely used, most widely

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used? As compared to?
BY DR. RESTAINO:
Q. That's the language that those researchers use, that it was the most -- what do you -- how do you interpret most widely used?
A. Most widely used. Do you have Reference 19? Because this statement is coming from the 19.
Q. Correct.
A. So I want to see the original articles. Do you have one?
Q. Well, no. In the original that underlying article might also reference another article which could reference another article. We're just going by this published article.
A. Then...
MS. MILLER: Is there a question pending?
DR. RESTAINO: It was an answer to his question.
MS. MILLER: I'm losing my mind here.

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DR. RESTAINO: The question pending is -- is his interpretation of most widely used tumor marker.
MS. MILLER: Do you understand the question that's pending for you? If you understand, great; I don't.
THE WITNESS: Okay. Back to the time. And do you have a reference? Let me take a look.
BY DR. RESTAINO:
Q. Okay. No, we don't have it.
A. Oh, you don't have it.
Q. No.
A. Okay. So you don't have the evidence to show, okay.
Then I believe that this is a common belief at that time, back to ten years.
Q. Okay.
A. Okay. And this is the biomarker for the therapeutic index, but nothing to -- to be related to screening,

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early lesions, pathogenesis. It just reflect how many tumor cell you have, how many tumor cell you have.
Q. Okay.
(Document marked for identification as Exhibit Shih-21.)
BY DR. RESTAINO:
Q. And I'll hand you what we've now marked as Shih-21. And this paper has been published in the International Journal of Cancer, lead author Kaaks, K-A-A-K-S. It's titled "Tumor-Associated Auto Antibodies As Early Detection Markers For Ovarian Cancer: A prospective evaluation." Published 2018.
And this, as the title suggests, was a prospective study, correct?
A. I need -- I never see this paper, okay. Let me take some time to read even the title.
Q. Doctor, while you are looking at that, look at where your

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fingers are on the bottom. Do you see the language right underneath your finger?
A. Which one?
Q. Down at the bottom of the page.
A. International Journal of Cancer?
Q. No. The -- the language from the journal underneath the -- what's new?
A. The box under the what's new?
Q. Under the box, yeah.
A. Okay. Okay. I have not go there yet, but we can start.
Q. Okay.
A. You can read to me.
Q. Okay. Sir, yeah, I was concerned only because the -- what I -- the only section that I wanted to read to you, I kept noticing your thumb was covering it.
A. Thank you very much for your

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help.
Q. On the -- on the bottom it states, "Cancer Antigen-125 (CA-125) is the best available biomarker for epithelial ovarian cancer, and the only marker tested in prospective screening trials so far."
Did I read that correctly?
A. That has been said here.
Q. Yes. And it --
A. But there is no reference, so I'm surprised. Where is -- is the basis coming from?
Q. Okay. Do you have any reason to -- to contradict them when they say it's the best available biomarker for epithelial ovarian cancer?
MS. MILLER: Objection.
THE WITNESS: This question is too general. I don't know if I can --
BY DR. RESTAINO:
Q. Okay. Do you disagree that that's the only marker tested across

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prospective screening?
A. Which --
MS. MILLER: Objection.
THE WITNESS: Same. I don't know what does that mean, it's too general. What do you mean?
BY DR. RESTAINO:
Q. What part don't you understand? Do you need different help with prospective or screening?
MS. MILLER: Object -- objection.
THE WITNESS: Where -- where are you, your prospective term coming from?
Could you pinpoint specifically which sentence you are talking about, please?
BY DR. RESTAINO:
Q. Yes, sir.
A. Okay.
Q. Down at the bottom. First column on the left, Cancer Antigen-125.
A. Yes, I saw that.

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Q. That's the best available biomarker for epithelial ovarian cancer. Published this year -- excuse me, 2018, correct?
A. No. This is -- refer the author's opinion as introduction. This is not based on real result. Okay.
Q. Okay.
A. So this is a part of introduction. They need to show the readers about why they want to do a study. And there is no citation. So I don't know where this come -- comes from.
Q. And there's no citation in your paragraph, in your expert report, where your -- where your contrary conclusions come from, are there -- is there, Doctor?
MS. MILLER: Objection.
THE WITNESS: Which?
MS. MILLER: Objection.
BY DR. RESTAINO:
Q. Your paragraph in your expert report does not contain a single

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citation, yet you are criticizing these individuals in a peer-reviewed publication for the lack of a citation. So where is your citation, sir?
A. Okay. So which part are you talking about?
Q. Your expert report. Irrelevance of 125 finding as you criticize Dr. Saed. You are putting down your subjective opinions in paragraph titled "Irrelevance of CA-125 Finding" without a citation, correct?
MR. LOCKE: Objection.
BY DR. RESTAINO:
Q. Is it correct? Do you have a citation?
A. They are different. They are different. They are different.
Q. Okay. Now I'd like to show you another paper we've marked as Shih-22.
(Document marked for identification as Exhibit Shih-22.)

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BY DR. RESTAINO:
Q. And, Doctor, the -- your -- your professional life is all about early detection of ovarian cancer, correct?
MS. MILLER: Objection.
BY DR. RESTAINO:
Q. Is that a main part of your professional life?
A. What do you mean professional life?
Q. The work that you do at Johns Hopkins?
A. I diagnose patients' tissues as well.
Q. Yes, I did -- I was -- I did not mean to demean all the work that you do.
A. So can you repeat your question.
Q. I'll strike the question.
MS. MILLER: Why don't we go on.
BY DR. RESTAINO:
Q. Exhibit Shih-22, "Early Detection of Ovarian Cancer" by Elias, et al., and this is published in Hematology, Oncology Clinics of North America.

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A. Thank you.
Q. You're welcome.
A. Early detection.
Q. Do you remember seeing this paper at all, Doctor?
A. No. This is in a very unusual journal. We usually -- as an ovarian cancer researcher, we really don't read that kind of journals.
Q. Okay. Are you speaking for all ovarian cancer researchers in the country?
A. No, just me. I say me. Of course.
Q. Okay. If you look at the key points --
A. I'm sorry, can I study the authors and this and that.
Q. Sure. Do you know any of the authors?
A. Again, I don't think the authors are important. The scientific content is more important for our discussion.
Q. I'm -- okay.
You asked if you could study the authors. So I was just asking if you know the authors.
A. I know the name of Bast.
Q. Okay. Underneath there, do you see the key points for the paper? Listed underneath the authors. And there's keywords, and then key points.
Do you see that, sir?
A. So there are four key points.
Q. Okay. First bullet point states, "Given the low prevalence of ovarian cancer, even among postmenopausal women (1:2,500), an effective screening strategy requires high sensitivity (greater than 75 percent) and extremely high specificity (99.7 percent)."
Did I read that correctly, sir?

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A. Yes.
Q. Do you agree with that statement, that an effective screening strategy requires high sensitivity, extremely high specificity?
A. So again, I don't know what kind of ovarian cancer they are talking about because for the detection screening, it's so important for the histological subtypes.
Q. And if you can turn to Page 906.
A. Okay. Nine -- okay.
Q. And there's a -- right above the Figure 1, there's a heading protein biomarkers.
Do you see that, sir?
A. Yes.
Q. And they write, "CA-125 remains the most sensitive and specific protein biomarker for detecting early stage disease in apparently healthy populations."
Did I read that correctly?

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A. It has been written this way.
Q. Okay. And this is a publication also in 2018 regarding CA-125, correct?
A. I don't believe this, this statement.
Q. Okay. Now, in your paper, you also discuss a paper by Urban, et al., U-R-B-A-N.
Do you recall that name?
A. Could you show me?
Q. Yeah, I'll look for it.
DR. RESTAINO: Jessica has much better luck finding these things than I do.
MS. MILLER: You want to know where he cites Urban in his report?
DR. RESTAINO: I think I'm seeing it.
BY DR. RESTAINO:
Q. Yes, on Page 12, top paragraph. In the middle of the

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paragraph, to the right of Gonzalez, et al. 2016, you start a sentence, "In another important study."
Do you see that, sir?
A. Yes.
Q. "In another important study, reported by Nicole Urban" -- U-R-B-A-N -- "et al., based on 74,786 Women's Health Initiative (WHI) observational study (OS) participants, the authors concluded that CA-125 and HE4 contribute significantly to a risk prediction classifier combining serum markers with epidemiologic risk factors. The hybrid risk classifier may be useful to identify postmenopausal women who would benefit from timely surgical intervention to prevent ovarian cancer."
Did I read that correctly, sir?
A. Yes, you did.
Q. And you described Urban as an important study, correct?
A. I did not cite this as

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important study.
Q. Well, you started off by -- I started off by reading, "In another important study."
A. Okay.
Q. Did you -- did you actually read the WHI observational study?
A. I remember that I read that before, but when I say important, is important in this context, okay.
It doesn't mean anything else. So you need to be careful. When I say important, you need to read the whole paragraph, and even the entire report to know what I say is important. You cannot just crop a sentence, one here, there, here. That's not fair.
Q. Okay. Doctor, I can only go by the words that you use in your expert report.
Now, if you -- this paper that we handed you, Urban, it's Exhibit 23, "Identifying Postmenopausal Women At Elevated Risk For Epithelial

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Ovarian Cancer."
MS. MILLER: Can we have a copy?
(Document marked for identification as Exhibit Shih-23.)
BY DR. RESTAINO:
Q. Doctor, if you turn to the second page -- well, first, on the front page, this is a 2015 paper, correct?
A. That's correct.
Q. So we're not as far back as 2008, nor are we as current as 2018, correct?
A. Yes.
Q. And if you turn to Page 254, which is the second page, and I'm going to try to draw your attention -- left paragraph, bottom -- I'm sorry. Left column, bottom paragraph, six lines up. On the right-hand side, you see CA-125?
A. Right.
Q. And they write, "CA-125 is a predictive marker for EOC that becomes

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increasingly sensitive with proximity to disease."
Doctor, what is meant by EOC?
A. This is not a regularly used term in ovarian cancer community. So I need to figure out what is their definition.
Q. Well, Doctor, this paper is published in Gynecologic Oncology.
And is it your opinion that oncologists and gynecological pathologists don't know what EOC stands for?
MS. MILLER: Objection.
THE WITNESS: Different --
MS. MILLER: Objection.
THE WITNESS: Different groups of people using different abbreviations. So this is a private abbreviation.
BY DR. RESTAINO:
Q. Okay. Do you understand when they use EOC here that they are

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utilizing that as, in the title, epithelial ovarian cancer?
A. So that would be where?
Q. Is that your understanding, EOC means epithelial ovarian cancer?
A. That's their definition and abbreviation.
Q. And so they write here that "CA-125 is a predictive marker for EOC that becomes increasingly sensitive with proximity to diagnosis." And then just below it in the final sentence, they say, "Both CA-125 and HE-4 show promise as risk and early detection markers."
Did I read that correctly?
A. It has been written in this way.
Q. Okay. And actually there they have Reference 16, and then they have References 20, 21, 22 and 23. So they have five references to support that statement, correct?
A. It depends on what -- what kind of references. Good or bad. I need

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to see them. Okay. 16.
Do you have those references, that would be wonderful for the discussion. By looking at the title I don't know the science quality inside this paper.
Q. Okay. Do you have any reason to believe that this paper in Gynecologic Oncology is misrepresenting what the references state?
MR. LOCKE: Objection.
THE WITNESS: I don't know how they interpret their reading and the interpretation. So I cannot answer that question. That's their written, that's their opinion, it's not my opinion.
BY DR. RESTAINO:
Q. Okay. I see. Okay. So, Doctor, it was okay for you to rely upon this paper, and for you to cite this paper in your expert report as an important study when you were discussing it in your expert report, but now in your

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deposition, now you can't rely upon anything that's published in this paper?
MS. MILLER: Objection.
MR. LOCKE: Objection.
MS. MILLER: That's not what he said. You are misstating his testimony.
If you -- would you like to explain?
THE WITNESS: Okay.
So you just tell me in the introduction, you crop the couple of sentences and ask me about the opinion.
But you know how many sentences in this article? You don't know, right? Many.
BY DR. RESTAINO:
Q. No. But I do know that you've quoted two sentences in your expert report from this sentence -- from this paper.
A. Okay. Let me -- let me go back and make sure.

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Q. Sure.
MS. MILLER: We are at exactly five hours. Do you want to take a break now?
DR. RESTAINO: I -- I do.
MS. MILLER: Six hours. I'm sorry, six hours. I just thought maybe this would be a good time for a last break.
DR. RESTAINO: Sure. One more paper to go through and we'll take a break.
THE WITNESS: Okay. All right.
The -- okay. Can I start?
BY DR. RESTAINO:
Q. Yeah, sure.
A. So the purpose I cite this paper --
Q. Yes.
A. -- is to show that talc use did not carry any significant -- or any risk for ovarian cancer. That's my purpose.

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Q. Okay.
A. In -- in terms of CA-125 as a biomarker is not relevant to talcum powder at all. Biomarker is just a serum -- is just a circulating proteins. It doesn't mean that is important for normal fallopian tube epithelium cells, to become p53 signature or STIC. So it's not totally relevant.
In early detection is a biomarker association does not mean there is a causal relationship.
Q. Okay.
(Document marked for identification as Exhibit 24.)
BY DR. RESTAINO:
Q. Doctor, one more paper in this area. You may recognize the title. "Critical Questions in Ovarian Cancer Research in Treatment: Report of the American Association For Cancer Research special conference."
Does that sound familiar to you, sir?

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A. I need to see it.
Q. Sure.
A. Yes, I'm one of the co-authors.
Q. That you are.
A. Yes.
Q. And if you look at the bottom of the first page. Very, very bottom, in the tiny little print, all the way down at the bottom, it says, "Received August 24, 2018. Revised December 17, 2018. Accepted 2019. And published online month 00 2019."
So this is a very current paper, correct?
A. I agree.
Q. Okay. And, Doctor, did you have any part to -- to play in the revised version that was submitted on December 17, 2018?
A. To be honest, I am on this as a co-author, because we participate in a meeting. And this is like a meeting report. So everybody talk about things,

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and so Dr. Bast, the first author as you can see here, the CA-125 discover person, and he write -- I think probably he wrote this paper by summarizing our opinion during the conference -- conference. Okay?

So after that, I did not see the revision and this and that. So I am participating in this as a co-author, because I contribute to the discussion during the -- during the symposium of ovarian cancer.

Q. Okay. If you -- if you turn to Page 8 of this paper?

A. 8?

Q. Yes, sir.

A. Okay. Yes.

Q. And on the right side where there's conflict of interest disclosure, your name is not listed, correct? Were you a retained expert for Johnson & Johnson while you were engaged in this process?

A. I think this is way before I

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am involved in this litigation.

Q. Okay. Now, if you -- on the left column, that's a section called "Conclusions," correct?

A. Correct.

Q. And in this paper that was published in 2019, this group including yourself write, "In answering these 'critical questions,' we have learned that screening algorithms measuring the trend of CA-125 values over time can achieve adequate specificity, but we must improve the sensitivity of panels of biomarkers for early detection of ovarian cancer, possibly utilizing autoantibodies, antigen-autoantibody complexes, and nucleic acid."

Did I read that correctly?

MS. MILLER: Objection.

THE WITNESS: I think this is Dr. Bast's opinion, because that's his research field exactly. And he is the author who wrote this paper.

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BY DR. RESTAINO:

Q. Okay. So, Doctor, reasonable scientists can reasonably disagree, correct?

MS. MILLER: Objection. Vague.

THE WITNESS: It's too vague. What's your question?

BY DR. RESTAINO:

Q. Okay. While you are disagreeing with Dr. Saed's use of CA-125 and I've now shown you four papers supporting the use of CA-125 including a 2019 paper for which you are a co-author.

MS. MILLER: Objection. Those papers did not use CA-125 in the same way as Dr. Saed. That is such a disingenuous question.

MS. PARFITT: It's objection to form.

BY DR. RESTAINO:

Q. Doctor, can reasonable scientists reasonably disagree?

MS. MILLER: Objection.

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THE WITNESS: No. It's based on biological plausibility and the specific question you want answered.

I'm asking, or we are addressing the early STIC and p53 signature in the fallopian tube, whether talc can cause ovarian cancer and cause the precursor. Now, you are diverting the discussion into the CA-125. And CA-125 is a biomarker for monitoring disease for -- this is well known.

So I don't know why this question is relevant. And this is -- should be not existent.

BY DR. RESTAINO:

Q. So when you disagree that CA-125 is a clinically irrelevant biomarker for ovarian cancer, you disagree with the authors that we've just discussed, right?

MR. LOCKE: Objection.

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MS. MILLER: Objection. I'm sorry.
THE WITNESS: Okay.
BY DR. RESTAINO:
Q. Go back to the paragraph in your expert report. "Irrelevance of CA-125," the final sentence, "Thus Dr. Saed's statement in the conclusion of the report that CA-125 is 'clinically relevant biomarker for ovarian cancer'" -- and there's your reference -- "'is misleading and data from CA-125 are not relevant to support the research and conclusion.'"
A. I'm sorry. Where are you? Which page?
Q. I'm sorry. Page 5.
A. Right.
Q. The paragraph -- second paragraph from the bottom, "Irrelevance of CA-125 Findings."
A. Oh, I know what's that. So you need to be careful for the context.
So why I want to say that is

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irrelevant of why we are discuss. That's why we want to bring the discussion relevant here.
What I say here is Dr. Saed treat ovarian cancer cell line which is total incorrect methodology, with talcum powder, Johnson & Johnson powder, and took CA-125. Then he misrepresented, totally wrong that CA-125 because of the increased CA-125, that talcum powder is a carcinogen, which is totally incorrect, in this specific context.
So don't -- you need to be careful about what you are referring to.
Q. When Dr. Saed states that CA-125 is a, "Clinically relevant biomarker for ovarian cancer," he is not being misleading, for we've just read four papers, including one by yourself, that supports the use, between 2008 and 2019, the use of CA-125 for the early detection of ovarian cancer, correct?
MR. LOCKE: Objection.
MS. MILLER: That's again

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mischaracterizing his testimony.
MS. PARFITT: It's "objection to form."
MS. MILLER: And as I said, you are mischaracterizing how Dr. Saed uses CA-125.
THE WITNESS: Right. You should read Dr. Saed paper.
BY DR. RESTAINO:
Q. Sir, I'm reading your expert report in your language.
A. My language is referring to Dr. Saed's. You see here my opinion about Dr. Saed's. So we need to go back to Dr. Saed's paper. And we can discuss. How about that?
Q. I'm just going by what you've stated in your expert report.
DR. RESTAINO: We can take our break now.
THE WITNESS: Okay. Sure.
THE VIDEOGRAPHER: The time is 4:56 p.m. We're going off the record.

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(Short break.)
THE VIDEOGRAPHER: The time is 5:14 p.m. We are back on the record.
BY DR. RESTAINO:
Q. Doctor, looking at your expert report, please, on the bottom of Page 5, you have a paragraph there which goes over to 6 titled "Extrapolation From an In Vivo Experiment," correct?
A. What I meant is -- let me see.
MS. MILLER: Are you just asking if those words are there?
DR. RESTAINO: Just directing him to that area.
MS. MILLER: Page 5.
DR. RESTAINO: Page 5 going over to Page 6.
MS. MILLER: Oh, okay.
BY DR. RESTAINO:
Q. Do you see that, Doctor?
A. Yes.
Q. And actually, you started

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off by saying, "What I meant is." Doctor, what did you mean in that paragraph?

A. I expressed my opinion about Dr. Saed's claims in his summary paragraph. And what he said, this is very important.

"This study has shown a dose-dependent significant increase in key pro-oxidants and concomitant increase in key anti-oxidant enzymes in all talc retreated cells, both normal and ovarian cancer, compared to their control."

But we know this is in vitro study.

What I mean is they don't have any in vivo support, because carcinogen, I think that's -- if you agree, that's the main things about the talcum powder issue.

So the carcinogen based on the definition from the dictionary or NCI, is the chemical compounds, reagents that can cause cancer, and of course

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cancer meaning from a tissue. So they did not show any evidence biologically plausible evident that talcum powder is -- can cause ovarian cancer.

This -- everything is just in vitro evidence.

Q. Yes, and in vitro means in essence either looking at a slide or a petri dish, correct?

A. No. Slide is human tissue. I think that's a tissue study. In vitro meaning -- we need to be careful here. We need to define this very well. In vitro meaning not inside animal tissue or human tissues. Everything is based on cell culture in petri dish, and you add the drug in the condition, un-physiologically high concentration. And you measure the proliferation, apoptosis, and that is exactly what Dr. Saed did.

Q. Okay. Now, Doctor, to be fair, in scientific research, it is not uncommon for a person or a team to

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conduct an in vitro study, determine the results of that study, and based upon the results, perhaps then say, now let's do an in vivo study and see if we see this in animals. And if so, and it's perhaps a treatment, now let's do a Phase I study, clinical study, and find out the dose or the safety parameters, and based upon that, do a Phase II study, and based upon that do a Phase III study. And perhaps in some cases even a Phase IV postmarketing study.

So that from in vitro to Phase IV is not uncommon in science research, correct?

MS. MILLER: Objection.

THE WITNESS: You are talking about general science?

BY DR. RESTAINO:

Q. Yes, sir.

A. So general science --

Q. Yes, sir?

A. -- cannot apply to the individual ones.

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For example, in this case, if we want to test talcum powder is carcinogenic at all, this kind of lousy science is not helpful at all. They -- they are just end -- without quotes, without evidence, cultured evidence to show anything biologically meaningful and any mechanism. It's just in vitro. And Dr. Saed -- go ahead.

Q. Okay. Okay. Well, as you write, the significance of the finding is unclear.

Well, the significance of every finding becomes clearer and clearer as we step up in the different studies. In vitro to in vivo or animal, to human testing, correct?

A. This depends on your in vitro study, how solid it is. How much biological plausibility it can offer. So if this is the case, then people will be -- love to test in vivo, in human trial. But in the first phase, like Saed's paper, they are filled with a lot

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of problems and the wrong methodologies. I don't think any people will look at this paper and will carry any meaningful significance biologically to them.

Q. You're purely speculating on what other readers are going to take away from this paper, aren't you?

MS. MILLER: Objection. Objection.

THE WITNESS: Which readers? Can you pinpoint which readers?

BY DR. RESTAINO:

Q. Any reader. When you say that, "I don't think any people will look at this paper," what people were you talking about?

MS. MILLER: Objection. That's --

MS. PARFITT: "Objection to form" is fine.

MS. MILLER: Thank you, Michelle.

MS. PARFITT: You're

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welcome.

THE WITNESS: People. What do you mean people? Where I said people, right? That's why --

BY DR. RESTAINO:

Q. Can we agree that --

MS. MILLER: You read back only half the sentence. That's --

BY DR. RESTAINO:

Q. Doctor, can we agree that there's no --

A. Can I see that?

Okay. The people here means the scientists who really read this paper, and I'm very sure they will still agree that this is really shocking paper to them, because there is no -- this is just like a script by some other party for litigation purpose.

Q. But, Doctor, it's not inappropriate to look at the results of an in vitro study, and then based upon those results, do the next study in line, perhaps an in vivo or animal study,

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correct?

MS. MILLER: Objection.

BY DR. RESTAINO:

Q. There's nothing inappropriate about that?

MS. MILLER: Objection.

THE WITNESS: I answer your question already.

BY DR. RESTAINO:

Q. Okay. Doctor, do you have an opinion on whether the talcum powder products that we are discussing in this case contain asbestos?

MS. MILLER: Objection.

THE WITNESS: I don't know.

BY DR. RESTAINO:

Q. Okay. Do you have an opinion as to whether the talcum powder products at issue in this case ever contained asbestos?

MS. MILLER: Objection.

THE WITNESS: I don't know.

BY DR. RESTAINO:

Q. Do you have an opinion on

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whether the talcum powder products at issue in this case contain fibrous talc also known as talc in an asbestiform habit?

MS. MILLER: Objection. Foundation.

THE WITNESS: This is beyond my expertise and you should ask mineralogist and a toxicologist, geologist.

BY DR. RESTAINO:

Q. Does that -- I'm sorry. Does that mean you don't have an opinion?

A. I already answered my question.

Q. Okay. Do you have an opinion on whether the talcum powder products at issue in this case contain -- ever contained fibrous talc, also known as talc in an asbestiform habit?

MS. MILLER: Objection.

THE WITNESS: Same answer to that previous question.

BY DR. RESTAINO:

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Q. Do you have an opinion on whether asbestos is a known carcinogen?
MS. MILLER: Objection.
THE WITNESS: I did not study asbestos.
BY DR. RESTAINO:
Q. Do you have an opinion on whether fibrous talc is a known carcinogen?
A. I did not study it either.
Q. Do you have an opinion on whether asbestos can cause ovarian cancer?
A. There is no credible science and cogent evidence. If you have one, please show it to me.
Q. Do you have an opinion on whether fibrous talc, also known as talc in an asbestiform habit, can cause ovarian cancer?
MS. MILLER: Object to form. I think you already asked this.
THE WITNESS: You asked me

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several times.
BY DR. RESTAINO:
Q. No.
A. Same answer.
Q. Okay. And do you have an opinion -- so your opinions in this case, is it fair to say, are limited to talcum powder products that do not contain asbestos or fibrous talc?
A. I cannot --
MS. MILLER: Objection. No, that is not what he said.
THE WITNESS: No.
MS. PARFITT: Objection to form is fine. Jessica, don't coach the witness.
MS. MILLER: He can't -- I'm not coaching the witness. He's mischaracterizing his testimony.
MS. PARFITT: He asked a question, asked an opinion. He said do you have an opinion.
MS. MILLER: No, he said it's fair --

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THE WITNESS: No.
MS MILLER: That's not what he said.
THE WITNESS: No.
BY DR. RESTAINO:
Q. I'll rephrase it. Do you have an opinion as to whether your opinions in this case are limited to talcum powder products that do not contain asbestos or fibrous talc?
MS. MILLER: Objection.
MS. SHARKO: I don't understand the question.
MS. MILLER: That's just an incomprehensible question.
THE WITNESS: Could you ask a question that is easily understood? The limitation was limited.
BY DR. RESTAINO:
Q. Do your opinions in this case -- are your opinions in this case limited to talc, talcum powder products, which do not contain asbestos?

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MS. MILLER: Objection.
THE WITNESS: So are you asking me whether this talc, talcum powder products contain asbestos?
BY DR. RESTAINO:
Q. No, sir.
A. But that's what you ask -- you are asking me.
Q. No, I'm asking you if your opinions in this case are limited to the evaluation of talcum powder products which do not contain asbestos.
MS. MILLER: Again, I'm going to object to that question. I think it's misleading. I think it's confusing. And I -- he said his opinions are related --
THE WITNESS: Okay. I'm here as expert to express my opinion on whether talcum powder can cause ovarian cancer. And also I bring up the issue of Dr. Saed's paper, which is

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really -- emperor has no clothes. There's no evidence. That is my position here today.
DR. RESTAINO: Move to strike as unresponsive.
BY DR. RESTAINO:
Q. Doctor, did you assume for purposes of your opinions today that talcum powder products do not contain asbestos?
MS. MILLER: Objection. Asked and answered in a different -- with different wording. And I feel like you're --
MS. PARFITT: Objection to form.
MS. MILLER: -- trying to confuse the witness because he's not --
MS. PARFITT: Object to form.
MS. MILLER: Because he doesn't have English as his first

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language.
DR. RESTAINO: Your expert.
MS. MILLER: So what?
DR. RESTAINO: So if he can't understand English that's not my problem.
MS. MILLER: No, it's not that he can't understand. It's that you are asking very confusing questions and repeating the same questions in multiple different ways in an attempt to confuse him.
MS. PARFITT: Counsel, object to form. Please. We're almost done.
THE WITNESS: Okay. So I'm so distracted. So could you ask one more time in a way that you think I will understand?
MS. SHARKO: Do you want -- do you want me to help you, Mr. Restaino --
DR. RESTAINO: Sure.
MS. SHARKO: Do you want me

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to help you? Because I can easily.
DR. RESTAINO: Sure.
MS. SHARKO: Dr. Shih was asked to assume talcum powder is what it is in the container and he was not asked to address asbestos or heavy metals or fragrances or all that. Just whatever the talcum powder is.
MS. PARFITT: That's not your question.
DR. RESTAINO: Yeah, yeah. Truthfully that's not my question.
MS. PARFITT: Thank you, Susan. I appreciate that.
MS. MILLER: That is exactly your question. You asked him what was --
MS. SHARKO: Then ask the question.
MR. LOCKE: Yeah, that's --
MS. PARFITT: Michelle, Could you please.

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(Whereupon, the court reporter read back the requested portion of testimony.)
MS. MILLER: Objection. Asked and answered.
THE WITNESS: I already answered that in the very beginning.
MS. PARFITT: Could you repeat your answer?
THE WITNESS: I already answered.
BY DR. RESTAINO:
Q. But what is your answer?
A. You can see in the transcript.
Q. It's your assumption that the talcum powder does not contain asbestos?
MS. MILLER: Objection.
BY DR. RESTAINO:
Q. Was that your answer?
MS. MILLER: Objection.
THE WITNESS: I already

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answered.
BY DR. RESTAINO:
Q. Doctor, are your opinions in this case limited to talcum powder products that do not contain fibrous talc?
MS. MILLER: Objection.
THE WITNESS: So based on my literature search and the Saed's paper, I reviewed those studies using talcum powder and the Johnson & Johnson's products in all the epidemiology research and the Saed research, in animal studies.
That's -- that's my knowledge about this talcum powder.
BY DR. RESTAINO:
Q. Okay. Doctor, have you heard a term "biologic plausibility"?
A. Yes.
Q. And what does that mean to you?

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A. I think I said that in the morning, probably forgot, that's fine. I can say that one more time.
Biological plausibility means credible science, cogent evidence to support the biological plausibility of statement. In this statement, is the talcum powder induced ovarian cancer. And I don't find any biological plausibility in this case.
(Document marked for identification as Exhibit Shih-12.)
DR. RESTAINO: Michelle, can we go ahead and mark this -- oh, it's already been marked. Forgive me. I'm sorry.
BY DR. RESTAINO:
Q. Shih-12.
MS. MILLER: I'm confused. How do you have it if you've already marked it?
MS. PARFITT: Premarked.
DR. RESTAINO: Because they

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were premarked earlier this morning. And we went -- I went out of my chronological plan.
MS. MILLER: Okay.
BY DR. RESTAINO:
Q. Doctor, this is a paper --
MS. MILLER: Do we have a copy?
DR. RESTAINO: Oh, I didn't give it to you.
MS. MILLER: I don't think I got one.
BY DR. RESTAINO:
Q. This is a paper titled "Papillary Tubal Hyperplasia: The Putative Precursor of Ovarian Atypical Proliferative (Borderline) Serous Tumors, Non-Invasive Implants, and Endosalpingosis."
E-N-D-O-S-A-L-P-I-N-G-O-S-I-S.
Lead author is Robert J. Kurman, correct?
A. Yes.
Q. And last named author is

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yourself, correct?
A. I am.
Q. And this is published in the American Journal of Surgical Pathology in 2011, correct?
A. Yes.
Q. And if you look down at the very, very last line in the abstract on the front page, you see, you and Dr. Kurman, et al., write, "We propose a model for the development of ovarian and extraovarian low grade serous proliferations (APST, non-invasive epithelial implants and endosalpingosis) that postulates that all of these lesions are derived from PTH, which appears to be induced by chronic inflammation. If this hypothesis is confirmed, then it can be concluded that low and high grade ovarian tumors develop from tubal epithelium and involve the ovary secondarily."
Did I read that correctly?
A. Correct.
Q. Doctor, in 2011 was it

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biologically plausible that chronic inflammation would initiate this pathology?
A. Say that one more time.
Q. In 2011, when you and Dr. Kurman, et al., wrote this paper, was it biologically plausible that chronic inflammation would initiate this pathology?
MS. MILLER: Which pathology?
DR. RESTAINO: The pathology that I just read about, described in his paper.
MS. MILLER: Objection.
THE WITNESS: This paper presents our hypothesis in 2011.
So how can science advances? It is because we have different findings, come out with hypothesis, or just generate hypothesis from nowhere.
Then scientists can decide to test this hypothesis using the

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correct methodologies to prove or to provide biological plausibility of this hypothesis. So that's what we meant here.
BY DR. RESTAINO:
Q. Okay. But you would not develop, nor would Dr. Kurman, a hypothesis that wasn't based on biological plausibility, would you?
MS. MILLER: Objection.
THE WITNESS: Can you say that one more time.
BY DR. RESTAINO:
Q. You would not develop, nor would Dr. Kurman, a hypothesis that wasn't based on biological plausibility?
MS. MILLER: Objection.
THE WITNESS: Okay. Biological plausibility should be more than hypothesis. And this is a hypothesis awaiting for proven -- not proven -- to support it by credible science in the future.

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So again, this is a hypothesis.
BY DR. RESTAINO:
Q. Did you think that your hypothesis was biologically plausible?
MS. MILLER: Objection.
THE WITNESS: I already say that. Biological plausibility should be more than hypothesis.
BY DR. RESTAINO:
Q. If you turn to Page 8 of this paper, sir, in the second paragraph, it starts on, "Based on the findings in this study."
Do you see that, sir?
A. Which page?
Q. Page 8.
A. Okay. Here you go.
Q. Yeah.
A. And which paragraph?
Q. Second paragraph.
A. Okay.
MS. MILLER: First full paragraph?

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BY DR. RESTAINO:
Q. First full paragraph. It says, "Based on the findings in this study."
Do you see that, sir?
A. Yes.
Q. Okay. "Based on the findings of this study, we propose the following model for the origin and development of the entire spectrum of pelvic low grade serous proliferations. Chronic inflammation induces a proliferation of tubal epithelium that could progress to PTH in some women."
Doctor, in 2011 when you wrote this, was it biologically plausible for chronic inflammation to induce proliferation of tubal epithelium?
MS. MILLER: Objection.
THE WITNESS: As we state -- so the answer is no. What we say, we propose it. We hypothesize this model for future scientists or pathologists to test. You have

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seen the right methodology. And to provide, like, for instance a mouse study, et cetera. I don't want to deliberate here too much.

This is hypothesis, for the future biological plausibility to provide the evidence.

So this is a hypothesis. And again, there's many hypothesis. I said this many times.

Biological plausibility should be more than hypothesis. You need to have credible science and a cogent evidence to support.

BY DR. RESTAINO:

Q. So, Doctor, on the bottom paragraph, of this, on the same page that starts, "In conclusion," in the third line down, you have a sentence that starts, "The process begins with chronic inflammation, leading to tubal hyperplasia, which, if it progresses to PTH, can shed and implant tubal

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epithelium on ovarian and peritoneal surfaces resulting in a variety of low grade serous proliferations. If this hypothesis is confirmed it would indicate that all ovarian tumors, low and high grade, originate from tubal epithelium and involve the ovary secondarily."

Did I read that correctly?

A. That's what we wrote.

Q. Okay. Now, Doctor, isn't it generally accepted today that ovarian serous tumors originate in the tubal epithelium?

A. Okay. So we have two things. You're talking about low grade serous carcinoma right, or are you talking about high grade serous carcinoma?

Q. You are talking about both in this paper, aren't you?

A. Okay. So for the low grades it is a hypothesis, right? We hypothesize this and that.

But for high grade serous

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carcinoma, we have a -- the mouse study, we put a TP53 mutation into the mullerian epithelial cells. And they develop STIC and they become cancer.

Q. Okay. Doctor --

A. And that's the cancer cell reports for several years ago. And that's the best evidence.

Q. After this paper was published --

A. Right.

Q. -- did you alone or with Dr. Kurman or anyone else test the hypothesis to determine whether -- when the process begins with chronic inflammation, if it did, in fact, lead to ultimately the development of low grade and high grade serous epithelial tumors?

MS. MILLER: Objection. I don't think that accurately states the hypothesis.

THE WITNESS: No. As you can see in this chart, low grade serous carcinoma, high grade

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serous carcinoma, they are totally different.

High grade serous carcinoma is a Type II. Low grade serous carcinoma is a Type I disease.

Okay. So their origin is fallopian tube. By their pathogenesis, molecular genetic changes, they are all different. So you cannot lump them together for discussion.

BY DR. RESTAINO:

Q. Okay. If you go back to Page 2 --

A. Which paper?

Q. -- of your paper, please. The one we are talking about with Dr. Kurman, the papillary studies. If you go to Page 2, back to the top. The very last sentence above the line states, "If this hypothesis is confirmed, it can be concluded that low and high grade ovarian tumors develop from tubal epithelium and involve the ovary

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secondarily."
Did you conduct a follow-up study to prove or disprove your hypothesis?
MS. MILLER: Objection.
BY DR. RESTAINO:
Q. It's just yes or no.
A. So again you are confused about low grade and high grade. They are two different diseases.
Okay. For the low grade is a hypothesis. And you know low grade serous carcinoma is only 5 percent of ovarian cancer. Really, really small population. So I don't know whether low grade serous carcinoma has been shown in any epidemiology studies, any epidemiology study break, high grade, low grade, clear cell endometriosis, and et cetera. Otherwise, I don't know what you are talking about.
Q. Well, I'm talking about what you wrote, sir.
A. Yes.

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Q. So I'm going to move to strike your answer, because there's no confusion on my part, because I can read English. And what's stated here is if this hypothesis is confirmed, then it can be concluded that low and high grade ovarian tumors developed from tubal epithelium and involve the -- the ovary secondarily. So I'm combining low grade and high grade because that's what's written here, correct, Doctor?
MR. LOCKE: Objection.
MS. SHARKO: Objection.
THE WITNESS: That's not how we meant.
BY DR. RESTAINO:
Q. Oh, so is it your testimony today that a future reader, when they read this sentence, should call you up and say, Dr. Shih, what did you mean by this?
A. No. This the --
MS. MILLER: Objection.
Give me time to object. That was

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obviously an objectionable question.
Objection.
BY DR. RESTAINO:
Q. Did the peer reviewers know what you meant?
MS. MILLER: Objection.
THE WITNESS: Who are the peer reviewers?
BY DR. RESTAINO:
Q. I'm sorry?
A. Who are the peer reviewers?
Q. Well, they are typically anonymous, aren't they?
A. Yes.
Q. So I wouldn't know that. But somebody peer reviewed this, don't you agree?
MS. MILLER: Objection.
THE WITNESS: That's not relevant to this question.
BY DR. RESTAINO:
Q. Okay. Doctor, in 2011, was it biologically plausible that low and

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high grade ovarian tumors stimulated by chronic inflammation develop in the tubal epithelium, was it just biologically plausible?
MS. MILLER: Objection.
Objection. Asked and answered.
THE WITNESS: No.
I answered your question.
BY DR. RESTAINO:
Q. Okay. When you submitted the paper for publication, did any peer reviewer come back and say, this is not biologically plausible, we're not going to publish this?
MS. MILLER: Objection.
THE WITNESS: Could you repeat that question one more time?
BY DR. RESTAINO:
Q. When you submitted the paper for publication.
A. Yes.
Q. Did any peer reviewer come back and say, this is not biologically

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plausible?
A. In the peer review systems, my -- I serve editor-in-chief. This is not our focus. We want to publish hypothesis, review articles, epidemiology study, which don't have any biological plausibility, right?
We publish all the data that is peer reviewed. So that's our job. It's not required, it's not required for any publication to need that biological plausibility.
DR. RESTAINO: Move to strike as unresponsive.
BY DR. RESTAINO:
Q. Do you know what the peer reviewers --
MS. MILLER: It was responsive.
THE WITNESS: Why, why, why.
BY DR. RESTAINO:
Q. Do you know what the peer reviewers did in this case, did anyone say to you, this is not biologically

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plausible?
MS. MILLER: Objection.
THE WITNESS: I think I answered your question.
BY DR. RESTAINO:
Q. I'm -- I'm sorry, you didn't.
Did you get something back from peer reviewers saying this is not biologically plausible, please provide more information or do this further study?
MS. MILLER: Objection.
THE WITNESS: I think I already answered your question.
Biological plausibility is not required for any publications.
MS. SHARKO: I can help you out. Dr. Shih --
THE WITNESS: Yeah.
MS. SHARKO: -- he's just asking you if any of the peer reviewers said that to you.
So if you remember what the

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peer reviewers said, then you should tell him that.
THE WITNESS: Oh, I cannot remember that.
BY DR. RESTAINO:
Q. Okay. And, Doctor --
DR. RESTAINO: Thank you, Susan.
BY DR. RESTAINO:
Q. If you would turn now to your expert report, Page 9.
A. Okay. I'm sorry. Which one, page?
Q. Page 9 of your expert report, I think it is.
The lack of sufficient evidence to support talc as a cause of ovarian cancer?
A. You mean the C, right, under the Section C? We are looking at different pages.
Q. Just give me a chance to get there. C, the lack of sufficient evidence to support talc as a cause of

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ovarian cancer.
Okay. In the middle paragraph, you have a section that starts "according to Merriam-Webster's dictionary."
Do you see that, sir?
A. Right.
Q. Okay. Then the final two sentences to the -- that starts to the right of Martincorema 2017, you write, "Thus, in order to prove that any substance is carcinogenic it is not sufficient to demonstrate exposure. One must also demonstrate that the exposure can cause biological effects and tissue/cellular changes (like precursor lesions)."
Did I read that correctly?
A. Yes.
Q. And is it still your opinion today that one must demonstrate the exposure causes biological effects and tissue/cellular changes?
A. Cause biological effects,

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meaning biological plausibility to support, to support this issue.
Q. I'm sorry, Doctor, you are not saying biological plausibility here. What you wrote here was very specific, that "in order to prove that any substance is carcinogenic, it is not sufficient to demonstrate exposure, one must also demonstrate the exposure can cause biological effects and tissue/cellular changes."
Is that still your opinion, sir?
A. You need to see why I say that. You cannot just quote -- quote one sentence.
You see my previous sentences. "Carcinogens cause cancer due to their ability to damage DNA," blah, blah, blah.
"Thus, in order to prove that any substance is carcinogenic, it's not sufficient to demonstrate exposure."
What I mean is the mere

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experience -- the appearance of something, like talcum powder, I don't -- I don't believe, I don't see any credible evidence, ever in the fallopian tube, beneath the epithelial cells, okay, if we assume, but this is not possible, assume it's there, it's not sufficient to demonstrate that it is causal. You need to provide biological evidence to support, for example.
You need to show that talcum powder existence, right, can support there is a carcinogenic effect on the p53 signature. And a -- and a STIC and a biological mechanism behind that. There's many biological mechanisms.
That's why I say in -- in reference to the previous sentence, that's what I said.
Q. Doctor.
A. Right.
Q. That's the exact argument tobacco industry made in the 1950s and the 1960s that one cannot rely upon

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evidence of -- of epidemiology exposure, that there had to be scientific evidence of mutagenic activity. Isn't that correct?
MR. LOCKE: Objection to form.
MS. MILLER: Objection.
MR. MIZGALA: Objection.
MS. MILLER: You got three objections at the same time there. Did you get them all?
THE WITNESS: Do you have the reference or documents for that?
BY DR. RESTAINO:
Q. Well, Doctor, I'll show you what I've been marked as Shih-26.
(Document marked for identification as Exhibit Shih-26.)
BY DR. RESTAINO:
Q. It's a Saturday, September 30, 1950, publication in the British Medical Journal titled "Smoking

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and Carcinoma of the Lung," by Richard Doll and Austin Bradford Hill.
A. Wow.
Q. Doctor, if you take a look at it, the --
A. Hold on a moment. I need to see British Medical Journal. 1950.
Q. Now, sir, you see on the right-hand column there's a heading possible causes of the increase?
A. Could you hold a moment. I need to see what is this article.
Q. What part -- what do you need to look up for this article?
A. I want to know --
Q. It's published in British Medical Journal in 1950. It's written by Sir Richard Doll and Sir Austin Bradford Hill. What else do you need to see?
MS. MILLER: Objection. Is that actually a question or are you just being argumentive? If you'd like him to answer, he can. But I'm guessing you're just being

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argumentative. Tempers are flaring. The day's been long.
DR. RESTAINO: We've got about nine minutes.
BY DR. RESTAINO:
Q. Doctor, look at, "Possible causes of the increase. Two main causes have from time to time been put forward."
A. Okay. I did not follow. I just want to see any reference, okay. That's a point.
Q. A pre-1950 reference is going to help you?
A. No, no. Whether they cite any references. That's what I'm going to. Okay.
This one, two, three, four, five, six, seven, eight references in 1947 and 1944, 1939. Okay. What's your question?
Q. Possible causes of the increase.
A. Wait, wait, wait a second. Okay.

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Q. Front page, right column. "Two main causes from time to time have been put forward: One a general atmospheric pollution from the exhaust fumes of cars, from the surface dust of tarred roads, and from gas-works, industrial plants, and coal fires; and to the smoking of tobacco."
Did I read that correctly?
MR. LOCKE: Objection.
MS. MILLER: I'm going to raise several objections here. The witness has never seen this. This is outside his area of expertise. You haven't given him time to read it. And you've plucked one sentence out of it in order to make some point, unclear. And I think that's grossly unfair.
THE WITNESS: This is 1950.
MS. MILLER: You can't ask a scientist to comment on one sentence --
MS. PARFITT: "Object to form," Counsel. You have really crossed the line on this last one. We've got seven minutes. Please, or I'll call Judge Pisano.
THE WITNESS: So before I can answer any question, I need to -- so which -- which sentence you are referring to?
BY DR. RESTAINO:
Q. Well, sir, I was referring to the fact that the two -- of the two --
A. Oh, the paragraph.
Q. -- causes listed there, one of them is smoking of the -- smoking of tobacco.
As a pathologist, in your medical school education and in your training as a pathologist, did you study the association of smoking and lung cancer?
MS. MILLER: So objection. You said two main causes. And we don't know of what.
DR. RESTAINO: I read them into the record, what they are.
MS. MILLER: Causes of what? You just pulled out a sentence that says "two main causes." Of what?
DR. RESTAINO: How about the title of the article?
MS. MILLER: Well, you didn't even put that. I mean, he hasn't had a chance to look at it.
THE WITNESS: So this is a few sentences. Do you know how many sentences here?
BY DR. RESTAINO:
Q. Yes.
A. How many sentences?
Q. I've read it.
A. Yeah, how many sentences?
Q. A lot.
A. Well, how many?
Q. Is it your opinion that --
MS. MILLER: Not going to argue.
BY DR. RESTAINO:

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Q. -- that the association with smoking and lung cancer established in the 1950s and 1960s by case-control epidemiological studies depended upon the molecular evidence that you put into your record that must be present for there to be an association?
MS. MILLER: Objection.
MR. LOCKE: Objection to form and beyond the scope.
MS. MILLER: Thank you. Because I've been chided for apparently objecting improperly.
MS. PARFITT: Counsel, I'm just following the CMO.
MS. MILLER: Did you guys follow the CMO when you were defending depositions?
BY DR. RESTAINO:
Q. Can you answer the question, Doctor?
A. I am a gynecology pathologist. My field of research is vulva, vagina, cervix, uterus, right

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fallopian tube, left fallopian tube, right ovary, and the left ovary.
Q. Okay. And, Doctor, in that paragraph that you wrote at the bottom of the page where you start with, "According to Merriam-Webster's dictionary," and you describe a carcinogen as a substance that causes cancer, every one of those anatomic parts that you just said are not in this paragraph, correct?
MS. MILLER: Objection.
BY DR. RESTAINO:
Q. This paragraph talks about cancer in general, does it not?
MS. MILLER: Objection.
MR. LOCKE: Objection.
MS. MILLER: There's two questions there.
THE WITNESS: You speak too fast. This embedded different questions.
BY DR. RESTAINO:
Q. Okay.
A. Could you dissect this out

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and ask me one by one? Thank you very much.
Q. Doctor --
A. Yes.
Q. -- carcinogen causes cancer due to their ability to damage the genome and induce a cancer driver but not passenger mutations that promote cancer development; is that correct?
A. I need to see that, please.
Q. Just read from your paper. I'm reading what you wrote.
A. Yeah, I need to -- do you remember when I said that, in what context? What kind of question you ask?
Q. You need to have context for knowing -- for answering whether or not the word ovary is in that paragraph?
MS. MILLER: Objection.
THE WITNESS: Ovary in the paragraph.
MS. MILLER: Please, Doctor, let me do my job.
THE WITNESS: Okay. Okay.

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What do you mean ovary in that paragraph? I'm confused.
BY DR. RESTAINO:
Q. Doctor, this paragraph describes what carcinogens are in a general sense, not limited to the genitourinary tracts of a woman, correct?
A. You mean this paragraph in -- in "Smoking and Carcinoma of the Lung"?
Q. No, Doctor.
A. Which -- which paragraph are you referring to?
Q. The paragraph we're reading from Page 9 of your expert report --
A. Page 9, okay.
Q. "Lack of sufficient evidence to support talc as a cause of ovarian cancer.
A. Where is that now?
Q. On Page 9, C.
A. Okay. C, yes.
Q. You asked me about letter C. Letter C, "The lack of sufficient

evidence to support talc as a cause of ovarian cancer."

In the paragraph, "according to Merriam-Webster's dictionary," you do not describe the ovaries, nor the genitourinary tract, but rather you discuss carcinogens and cancer in a general sense, do you not?

MS. MILLER: Objection.

THE WITNESS: Okay. So your question is you talk about the definition of the carcinogen and I did not have over here. And you said this is the general description.

BY DR. RESTAINO:

Q. Correct? Correct?

A. That's from the definition of the dictionary.

Q. So is your opinion outside the genitourinary tract, but as cancer in general, that one must also demonstrate exposure can cause biological effects and tissue/cellular changes like precursor

lesions before you can make a causal connection between an environmental carcinogen and cancer?

A. No --

MR. LOCKE: Objection.

MR. MIZGALA: Objection.

BY DR. RESTAINO:

Q. Okay.

A. Is not must. Is has the biological plausibility to support. That's what I mean.

DR. RESTAINO: Okay. I think we're done.

MS. SHARKO: Thank you very much.

DR. RESTAINO: No further questions.

THE VIDEOGRAPHER: The time is 6:00 p.m. March 26, 2019. Going off the record.

This ends the videotaped deposition.

(Excused.)

(Deposition concluded at

approximately 6:00 p.m.)

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, IE-MING SHIH, M.D., Ph.D., have the opportunity to read and sign the deposition transcript.

MICHELLE L. GRAY,
A Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter and Notary Public
Dated: March 27, 2019

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

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Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, 1 - 449, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

IE-MING SHIH, M.D., Ph.D. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

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Notary Public

LAWYER'S NOTES

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